To,

The Chairperson DTAB,
Director General of Health Services (DGHS),
Ministry of Health and Family Welfare
Govt. of India,
Nirman Bhawan, New Delhi-110011.

Subject: Submission of report by Sub-committee constituted by DTAB for examination of cases of banning of 344 FDCs + 05 FDCs prohibited vide S. O. No. 705(E) to 1048 (E) dated 10.03.2016 and S. O. No. 1851 (E) to 1855(E) dated 08.06.2017-regarding.

Sir,

Director General of Health Services, Chairperson DTAB vide order no. 18-04/2018-DC dated 19.02.2018 constituted a sub-committee under the chairpersonship of Dr. Nilima Kshirsagar, Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Delhi to relook into the cases of banning of 344 FDCs + 05 FDCs prohibited vide S. O. No. 705(E) to 1048 (E) dated 10.03.2016 and S. O. No. 1851 (E) to 1855(E) dated 08.06.2017 by the Central Government.

The Sub-Committee examined all the 344 FDCs + 05 FDCs as per the Terms of Reference. The Sub-Committee also heard the petitioners/appellants including AIDAN. The Sub-Committee after detailed deliberation made its recommendations against each FDC.

The detailed report along with the recommendations on each FDC is enclosed herewith. On behalf of the committee, we sincerely thank DTAB for giving this opportunity.

Yours Sincerely,

19.7.18.

Dr. Nilima Kshirsagar
Chair in Clinical Pharmacology,
Indian Council of Medical Research (ICMR),
Delhi

Report of the DTAB subcommittee appointed on 19.02.18 to examine the matters related to 344 plus 5 FDCs in compliance with the Hon. Supreme court order dated 15.12.2017

INDEX

Section No.	Section	Page No.
A	Executive Summary	1
B	Detailed Report	3
1	Background	3
1.1	Parliamentary Standing Committee Report and Action Taken	3
1.2	Hon'ble Supreme Court judgement (relevant excerpts)	4
2	Appointment of Subcommittee and Terms of Reference (ToR)	6
3	Working of Subcommittee	9
3.1	Meetings	9
3.2	Procedure followed 3.2.1: Information sought from Appellant including AIDAN 3.2.2: Hearing Given 3.2.3: The AIDAN Hearing 3.2.4: Assessment • Information Reviewed • Criteria for Assessment • Comments on Information received from appellants	9 9 12 14 14 15 19
4	Recommendations for each FDC/ Appellant with grounds/reasons for attracting three factors and grounds/ reasons for recommendation.	25
4.1	Explaining the Layout of Table 8 that gives the FDC wise recommendations	25
4.2	FDC wise Recommendation (Table 8)	26
5	Bibliography	608
6	Appendix	616
6.1	Office memorandum F. No. 18-04/2018-DC dt. 19.02.2018	617
6.2	Minutes of the Meetings (including Annexures A and D) of the subcommittee	618
6.3	Public Notices put up at the CDSCO website inviting appellants to provide information about the FDCs and informing dates of Hearing	657
7.0	Group photograph of the subcommittee and brief note about the subcommittee members	688

A. Executive Summary

Parliamentary standing committee on Health and family welfare in its 59th report observed that some state licensing authorities had issued manufacturing licenses for several fixed dose combinations without prior clearance from Central Drugs Standard Control Organization (CDSCO), resulting in availability of many Fixed Dose Combinations (FDCs), which have not been tested for efficacy and safety, putting patients at risk.

With recommendations from committees (10 Expert Committee, Kokate Committee, New Drugs Advisory Committee, NDAC), CDSCO prohibited manufacture for sale, sale and distribution of 344+ 5 FDCs in public interest. In view of stakeholders writ petitions in different high court and orders there from, Union of India filed special leave petition before the Hon. Supreme Court. The Hon. Supreme Court gave its judgement on 15.12.2017, pursuant to which Drug Technical Advisory Board (DTAB) appointed a subcommittee to relook at the FDCs and give its recommendations.

DTAB Subcommittee and co-opted experts as per the terms of references held 41 meetings. It reviewed the information received from the appellants/ applicants/ All India Drugs Action Network (AIDAN) (812 representations for 184 FDCs), hearing (from 467 companies for 156 FDCs) and publically available literature in scientific peer reviewed journals, relying more on meta-analysis, Cochrane reviews and standard treatment guidelines by national/ international (followed in India) organizations and WHO authorities.

Adequate time and opportunities were given to the appellants/AIDAN to provide justification for their claims about each and every FDC.

Pursuant to the Supreme Court order, the subcommittee considered risk, therapeutic value and therapeutic justification for ingredients of the FDC as per CDSCO and WHO guidelines. It considered whether there is a need to prohibit or would restriction/ regulation be sufficient in public interest. As per the orders of the Hon. Supreme Court, the subcommittee specifically in its report has given grounds and reasons for attracting the three factors stated above and the grounds and reasons for its recommendations, as per the Drugs and Cosmetics (D & C) Act, guidelines and court orders.

The subcommittee noted that most appellants had not generated safety and/ or efficacy data of their own for their FDCs. The published literature they provided to justify the FDC was not relevant (epidemiological data not from India), and they relied on a few

biased studies (instead of meta-analysis and Cochrane reviews). Indications mentioned were too broad/ absurd/ vague, and were not as per the treatment guidelines. For most FDCs, their use would lead to unnecessary overuse and the patients would be exposed to the risk of multiple ingredients when one would suffice. In FDCs where there is a dosing mismatch among the ingredients; FDC use would result in toxicity (wherein the ingredient is being administered more frequently than required) or lack of effect (wherein the ingredient has been administered less frequently than required) An inability to adjust doses of individual ingredients is specially risky, if an ingredient has a narrow safety margin. Appellants claimed safety by quoting OTC products in UK or USA market, ignoring the lacunae in the OTC system, label requirements of OTC products (e.g. not for children under 12 years of age), lack of efficacy and withdrawal by innovator of some products. Some appellants wished to change indication and/ or carry out studies in support of their respective FDCs. They were advised to follow D&C Act for new drugs.

As per the Supreme Court judgement, AIDAN was given a hearing. The AIDAN in its hearing informed various issues relating to the FDCs.

On evaluation of 349 (344+5) FDCs as per the Supreme Court order and as per the minutes of the DTAB meeting, the subcommittee has recommended that 343 FDCs be prohibited and that 6 may be restricted/ regulated. Three needed to be restricted for specific indications. Three other FDCs were recommended to be restricted to specific quantities/ strengths of ingredients and for specific indications.

The subcommittee acknowledges gratefully DTAB for the opportunity it has given to the subcommittee members to review the FDCs, The subcommittee is grateful to the Drug Controller General (India) DCGI and his office staff for their help and support, to the learned subject experts for giving a distillate of their wisdom, knowledge and experience. The subcommittee also thanks the appellants (including AIDAN) for assisting the subcommittee by providing information about the FDCs and evidence for consideration.

The subcommittee has worked within the ambit of the Supreme Court order and guidance provided by the DTAB. It is hoped that the subcommittee's report would be helpful for the evaluation of FDCs in future, as well.

B. Detailed Report

1. Background

1.1 Parliamentary standing committee report and action taken

The Department-based Parliamentary Standing Committee (PSC) on Health and Family Welfare in its 59th Report on the Functioning of the Central Drug Standards Control Organization (CDSCO) observed, that some State Licensing Authorities had issued manufacturing licenses for several Fixed Drug Combinations (FDCs) without prior clearance from the Central Drug Standards Control Organization (CDSCO) and that this had resulted in the availability of many FDCs in the market which have not been tested for efficacy and safety putting patients at risk. As per the action taken report (ATR), the Drug Controller General of India (DCGI) vide letter dated 15.01.2013 requested the Drug Controllers of all the states and union territories to direct the concerned manufacturers under their respective jurisdiction to prove the safety and efficacy of such FDCs that were licensed by the State Licensing authorities (SLAs) prior to 01.10.2012 without obtaining the approval of the DCGI. This information was to be provided within a period of 18 months; failing which, the CDSCO stated that such FDCs would be considered for being prohibited for manufacture and marketing in the country.

Consequent to this, the CDSCO received approximately 6320 applications. The CDSCO constituted 10 Expert Committees on 03.02.2014 with the approval of the Ministry of Health. These Committees were tasked with examining the safety and efficacy of these FDCs. However, these committees could examine only about 295 applications. Subsequently, the Central Government appointed another Expert Committee under the chairmanship of Professor C. K. Kokate to examine the matter in a timely manner. The Committee was assisted by eminent experts in different therapeutic areas, who were drawn from premier Medical Institutions and Hospitals of the country.

Based on the recommendations of the Professor Kokate Committee, the Central Government vide Gazette Notifications S. O. Nos. 705(E) to 1048(E) dated 10.03.2016 prohibited the manufacture for sale, sale and distribution for human use of 344 FDCs with immediate effect in public interest, as use of these FDCs was likely to involve risk to human beings when safer alternatives for these FDCs were available. Further, in pursuance of the action taken note on the 59th PSC report, based on the recommendations of the New Drug Advisory Committee/ Subject Expert Committee constituted by the Central Government, the Central Government vide Gazette Notifications S. O. Nos. 1851(E) to 1855(E) dated 08.06.2017 prohibited the

manufacture for sale, sale and distribution for human use of 5 FDCs with immediate effect in public interest.

However, several stakeholders filed writ petitions in different High Courts across the country and the said notification was quashed by the Hon'ble High Court of Delhi vide its order dated 01.12.2016. The Union of India challenged the order of Delhi High Court before the Supreme Court by a Special Leave Petition (SLP).

1.2 Hon. Supreme Court Judgement (relevant excerpts)

The Hon. Supreme Court of India gave its judgement on 15.12.2017. The Hon. Supreme Court stated that:

32. This course is that instead of now remitting the matter back to the Delhi High Court for an adjudication on the other points raised in the writ petitions, the case of 344 FDCs that have been banned, plus another 5 FDCs that have been banned, which comes to 349 FDCs, (barring 15 FDCs that are pre- 1988 and 17 FDCs which have DCG(I) approval) pursuant to the Kokate Committee report, by notifications of the Central Government under Section 26A of the Drugs Act, should be sent to the DTAB, constituted under Section 5 of the Drugs Act, so that it can examine each of these cases and ultimately send a report to the Central Government. We reiterate that only on the peculiar facts of these cases, we think that such a course commends itself to us, which would obviate further litigation and finally set at rest all other contentions raised by the petitioners. We say so because we find that the Kokate Committee did deliberate on the 344 FDCs plus 5 FDCs and did come to a conclusion that the aforesaid FDCs be banned, but we are not clear as to what exactly the reasons for such conclusions are, and whether it was necessary in the public interest to take the extreme step of prohibiting such FDCs, instead of restricting or regulating their manufacture and supply. In order that an analysis be made in greater depth, we, therefore, feel that these cases should go to the DTAB and/ or a subcommittee formed by the DTAB for the purpose of having a relook into these cases. It is important, however, that the DTAB/ subcommittee appointed for this purpose will not only hear the petitioners/appellants before us, but that they also hear submissions from the All India Drugs Action Network. The DTAB/ subcommittee set up for this purpose will deliberate on the parameters set out in Section 26A of the Drugs Act, as follows:

33. First and foremost in each case, the DTAB/ subcommittee appointed by it must satisfy itself that the use of the Fixed Dose Combinations (FDC) in question is likely to involve any one of the aforesaid three things: (a) that they are likely to involve any risk to human beings or animals; or (b) that the said FDCs do not have the therapeutic

value claimed or purported to be claimed for them; or (c) that such FDCs contain ingredients and in such quantity for which there is no therapeutic justification.

34. The DTAB/ subcommittee must also apply its mind as to whether it is then necessary or expedient, in the larger public interest, to regulate, restrict or prohibit the manufacture, sale or distribution of such FDCs. In short, the DTAB/ subcommittee must clearly indicate in its report: (1) as to why, according to it, any one of the three factors indicated above is attracted; (2) post such satisfaction, that in the larger public interest, it is necessary or expedient to (i) regulate, (ii) restrict, or (iii) prohibit the manufacture, sale or distribution of such FDCs.

35. The DTAB/ subcommittee must also indicate in its report as to why, in case it prohibits a particular FDC, restriction or regulation is not sufficient to control the manufacture and use of the FDC. We request the DTAB/ subcommittee to be set up for this purpose to afford the necessary hearing to all concerned, and thereafter submit a consolidated report, insofar as these FDCs are concerned, to the Central Government within a period of six months from the date on which this judgement is received by the DTAB. We may also indicate that the Central Government, thereafter, must have due regard to the report of the DTAB and to any other relevant information, and ultimately apply its mind to the parameters contained in Section 26A of the Drugs Act and, accordingly, either maintain the notifications already issued, or modify/ substitute them or withdraw them.

36. With these directions given on the peculiar facts and circumstances of these cases, the appeals are disposed of.

37. Insofar as the drugs that have been banned and which were manufactured pre 21st September, 1988, a list of 15 such drugs has been given to us by Mr. Kapil Sibal, learned senior counsel for the respondents. We set aside the Central Government notifications banning them as these cases were never meant to be referred to the Kokate Committee. It will be open, however, for the Central Government, if it so chooses, de novo, to carry out an inquiry as to whether such drugs should be the subject matter of a notification under Section 26A of the Drugs Act.

38. Insofar as the list of 17 cases handed over by Shri Sibal, in which DCG(I) approvals have allegedly been granted, we are of the view that since the Parliamentary Standing Committee itself refers to DCG(I) approvals and the manner in which they were granted, we do not accede to Mr. Sibal's request that these 17 cases be kept outside the purview of the fresh look that has to be given by the DTAB/ subcommittee in these cases.

2. Appointment of the subcommittee by the DTAB and its Terms of Reference (TOR)

In the 78th meeting of the Drugs Technical Advisory Board (DTAB) which was held on 12th February 2018 under the Chairmanship of the Director General of the Health Services; the Board deliberated on the directions of the Hon'ble Supreme Court of India dated 15.12.2017 pertaining to the notifications issued by the Govt. of India prohibiting the manufacture, sale and distribution of 344 FDCs plus 5 FCs vide S. O. Nos. 705 (E) to 1048 (E) dated 10.03.2016 and S. O. Nos. 1851 (E) to 1855 (E) dated 08.06.2017, respectively. The Board after consideration constituted the following subcommittee under the Chairmanship of Dr. Nilima Kshirsagar to examine the banned 344 FDCs+ 5 FDCs:

"1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Delhi, (Chairman)

2. Dr. Rao V. S. V. Vadlamudi, President, Indian Pharmaceutical Association, Telangana. (Member)

3. Shri. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member)

4. One representative from Indian Medical Association, New Delhi (Member)

5. One representative from Indian Medical Association, Mumbai (Member)

6. One Clinical Pharmacologist (Member)

7. Shri. Sanjeev Kumar, DDC (I) CDSCO (HQ) (Convener)

The committee may co-opt subject experts as and when required. Subcommittee shall submit the report in three months for consideration of the DTAB".

Based on the decision, vide office memorandum (No. 18-04/2018-DC dated 19 Feb 2018), the subcommittee of the following members was constituted (Office memorandum F. No. 18-04/2018-DC dated 19 Feb 2018):

Table 1:

Constitution of the subcommittee appointed by the Drugs Technical Advisory Board (DTAB)

1	Dr. Nilima Kshirsagar The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Delhi	Chairperson
2	Dr. Rao V. S. V. Vadlamudi President, Indian Pharmaceutical Association Dr T. V. Narayana, President, Indian Pharmaceutical Association (From 12th June 2018)	Member
3	Shri O. S. Sadhwani Joint Commissioner, Food and Drugs Authority (FDA), Maharashtra	Member
4	Dr. R. N. Tandon Honorary Secretary General, Indian Medical Association (IMA), New Delhi	Member
5	Dr. Agam Vora Org. Secretary, Indian Medical Association (IMA), Mumbai	Member
6	Dr. Nirmala Rege Professor and Head, Department of Pharmacology and Therapeutics, Seth G. S. Medical College, Mumbai	Member
7	Shree Sanjeev Kumar, Deputy Drugs Controller, CDSCO (HQ)	Convener
8	Dr. Sandeep B Bavdekar Former Professor and Head, Department of Pediatrics, T. N. Medical College and B. Y. L. Nair Charitable Hospital, Mumbai	Co-opted Member by Chairperson

The DTAB prescribed the following Terms of Reference for the Subcommittee:

[1] The Committee may co-opt subject experts as and when required

[2] The Committee shall examine the issue of the cases banning of 344 FDCs+ 5 FDCs on the directions of the Hon. Supreme Court

[3] The Committee shall furnish its report within three months of the date of issue of Office Memorandum

[4] The TA/ DA for non- official members in this connection shall be paid as per Government of India norms and will be borne from the Indian Pharmacopeia Commission (IPC) budget. The air journeys should be performed by Air India flights only and the air tickets, if purchased through agent, should be purchased

through M/s Balmaer and Co., who is authorized Government agent for this purpose.

[5] All the members of the subcommittee shall follow the principle of confidentiality

[6] The Experts nominated as members for this subcommittee shall not have any conflict of interest.

The office memorandum delineating the DTAB decision was issued on 19.02.2018 (Appendix 6.1).

In the 79th meeting held on 16th May 2018, the DTAB considered the representations of M/s Abbott Health Care Pvt. Ltd. requesting to exclude 15 FDCs approved prior to 1988 and 17 FDCs which were approved by DCG(I), from the list of FDCs in the purview of subcommittee, constituted for the purpose as per the directions contained in the Hon. Supreme Court judgement were considered. The DTAB's decision is recorded as follows: "The DTAB members deliberated the issues and were of the view that the subcommittee shall submit the report of all (344 + 05) FDCs again as per the directions from Hon. Supreme Court judgement which also includes the 15 FDCs approved prior to 1988 and 17 FDCs approved by DCG(I). Accordingly, the decision after submission of the report by the subcommittee would be conveyed to the Ministry of Health and Family Welfare."

3. Working of subcommittee

3.1 Meetings held by the subcommittee

The subcommittee held its meetings on 01.03.2018 and 20.04.2018 at the Conference Hall, FDA Bhavan, New Delhi (to decide procedures to be followed and experts to be coopted. Subsequently 39 meetings were held to review the information submitted by the appellants and to give hearing and to finalize recommendation and report. (Minutes of the meetings including Annexures A and D, Appendix 6.2)

3.2 Procedure followed by the subcommittee

3.2.1 Information sought from the Appellants including AIDAN

As decided by the subcommittee, relevant information and documents pertaining to FDC were sought from the appellants/ petitioners in a semi-structured format as per Annexure A) by sending letters as well as by putting up the request on the CDSCO website (Appendix 6.3 public notice). The AIDAN was requested to submit information as per Annexure D)

The appellants/ petitioners and AIDAN were provided time up to 7th April 2018. On request from AIDAN, it was later extended for all to 4th June 2018. .

Information received was scrutinized, compiled and reviewed. Subsequently more information was received during hearing and even thereafter up to 26.6.2018, which was also incorporated in the compilation and review.

3.2.2 Hearing given:

As per Hon Supreme Court's order, to give hearing to the appellants/petitioners including AIDAN, a schedule of hearing as per the Statutory Order (S.O.) number was displayed on the CDSCO website (public notice Appendix 6.3) and they were also informed by sending a letter. The hearings were held from 5th- 22nd June 2018. The subcommittee members and co-opted experts gave the Hearing.

Table 2: List of co-opted experts

	Name, designation and affiliation of the co-opted experts
1.	Dr. Subhash Giri, Director and Professor, Department of Medicine, University College of Medical Sciences (UCMS), New Delhi
2.	Dr. Renuka Munshi, Associate Prof. and In-Charge of Department of Clinical Pharmacology, B. Y. L. Nair Charitable Hospital, Dr. A. L. Nair Road, Mumbai
3.	Dr. Mira Desai, Professor and Head, Department of Pharmacology, BJ Medical College, New Civil Hospital, Asarwa, Ahmedabad, Gujarat
4.	Dr. Subodh Kumar, Assistant. Professor, Department of Pulmonary Medicine, All India Institute of Medical Sciences, Rishikesh, Uttarakhand
5.	Dr. B. Gupta, Professor of General Medicine, North Delhi Medical College and Hindu Rao Hospital, New Delhi
6.	Dr. Sujith Chandy, Professor of Pharmacology, Christian Medical College and Hospital, Vellore
7.	Dr. Sushant H. Meshram, Professor of Pulmonary Medicine, Government Medical College and Hospital Nagpur
8.	Dr. Deepak Aggarwal, Associate Professor, Pulmonary Medicine, Govt. Medical College, Chandigarh
9.	Dr. Anant Mohan, Additional Professor, Pulmonary Medicine, All India Institute of Medical Sciences (AIIMS), New Delhi
10.	Dr. Dinesh Badyal, Prof and Head, Department of Pharmacology, Christian Medical College and Hospital, Ludhiana
11.	Dr. V. K. Sharma, Professor and Head, Dept. of Dermatology, All India Institute of Medical Sciences (AIIMS), New Delhi.
12.	Dr. K. M. K. Reddy, Professor and Head, Department of Cardiology, Osmania Medical College, Hyderabad
13.	Dr. Sanjeev Handa, Professor and Head, Dept. of Dermatology, Venereology and Leprology, Post-graduate Institute of Medical Education and Research (PGIMER), Chandigarh
14.	Dr. Suparna Chatterjee, Professor, Dept. of Pharmacology, Institute of Post Graduate Medical Education and Research, Kolkata
15.	Dr. Rohit Saxena, Professor of Ophthalmology, Dr. R. P. Centre for Ophthalmic sciences, AIIMS, Delhi
16.	Dr. Arvind Kairo, Assistant Professor, Department of Otolaryngology, Head and Neck Surgery, All India Institute of Medical Sciences (AIIMS), New Delhi
17.	Dr. Chetna Desai, Professor of Pharmacology, BJ Medical College, Ahmedabad
18.	Dr. Harshad Devarbhavi, Professor of Gastroenterology, St. John's Medical College and Hospital, Bangalore

19. Dr Santanu Tripathi, Professor of Clinical Pharmacology, Calcutta School of Tropical Medicine, Kolkata
20. Dr. Anup Kumar Kundu, Prof & Head, Dept. of Urology, IPGMER & SSKM, Kolkata
21. Dr. Pikee Saxena, Professor, Dept. Of Obstetrics & Gynaecology, Lady Harding Collage, New Delhi
22. Dr. Debashish Choudhary, Director-Professor & HOD of Neurology, GB Pant, New Delhi
23. Dr. Kameshwar Prasad, Professor and Head, Department of Neurology, All India Institute of Medical Sciences (AIIMS), New Delhi
24. Dr. Abhishek Agarwal Associate Professor of Medicine, Sawai Man Singh Medical College, Jaipur, Rajasthan
25. Dr. Bikash Medhi, Professor of Pharmacology, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh
26. Dr. Vyankatesh Shivane, Consultant Diabetologist, King Edward Memorial Hospital, Parel, Mumbai
27. Dr. Rajesh Khadgawat, Professor of Endocrinology, All India Institute of Medical Sciences, (AIIMS), New Delhi
28. Dr. Rajesh Rajput, Senior Professor and Head, Department of Endocrinology, Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences (PGIMS), Rohtak, Haryana
29. Dr. Avijit Hazra, Professor of Pharmacology, Institute of Post Graduate Medical Education and Research (IPGMER) & SSKM, Kolkatta
30. Dr. R. K. Arya, Consultant and Head, Department of Orthopaedics, Ram Manohar Lohia Hospital (RML), Baba Kharak Singh Marg, New Delhi
31. Dr. B. C. Sharma, Professor of Gastroenterology, G. B Pant Hospital, New Delhi
32. Dr. Vijay kumar Jain, Associate Professor of Orthopedics, Ram Manohar Lohia Hospital, New Delhi
33. Dr. Smita N. Deshpande, Professor and Head, Department of Psychiatry, Dr. Ram Manohar Lohia Hospital and PGIMER, New Delhi.
34. Dr. Shubhra Gill, Associate Professor, Dept. of Prosthodontics, Maulana Azad Medical College, New Delhi
35. Dr. VP Gupta, Director Professor & HOD Ophthalmology, Principal, UCMS, Delhi

The appellants presented their case for each FDC separately. If some appellants wished to make a joint/ common presentation for a particular FDC under the statutory order, that was allowed.

During the hearings, the appellants were informed of the Supreme Court judgement. They were informed of the relevant grounds for concerns pertaining to

their FDCs. They were given an opportunity to provide their justification for the FDC and were given more time (if requested by them) to submit any more relevant information they wished to provide.

3.2.3 The AIDAN hearing

The All India Drugs Action Network (AIDAN) submitted their information in Annexure D and also projected its views during the hearing. It stated that the WHO Essential Drug list (WHO-EDL) and those in the National List of Essential Medicines (NLEM) have a very limited number of FDCs. While conceding that there could be other rational FDCs which are not in NLEM or WHO-EDL, it stated that this should be decided on the scientific criteria and WHO guidelines by an expert body such as the current subcommittee of the DTAB. It also opined that the 344+ 5 FDCs currently under review by the subcommittee constitutes only a part of the problem and that there is a need to eliminate all the FDCs (including those beyond the 344 referred to above) in one go.

The AIDAN listed some of the difficulties it faced while providing opinion about individual FDCs. It pointed out that the licensing authority/ approving authority has not approved or notified the indication(s) for which several FDCs have been approved. In the absence of such information, it is difficult for them to comment upon the desirability of various ingredients in an FDC and that of the FDC itself or of the therapeutic value of the FDC.

The AIDAN, while interpreting the powers under Section 26A of the Drugs and Cosmetics Act stated that the onus of proving the rationality of an FDC rests with the manufacturer. It stated that if an FDC does not have acceptable efficacy, safety, therapeutic justification, there is no possibility of regulation of an FDC, but will have to be prohibited. It also pointed out that the following groups of FDCs are irrational:
FDCs of

(a) antimicrobials with anti-diarrheals, vitmins and corticosteroids
(b) analgesics with analgesics or anti-inflammatory drugs
(c) analgesics with other medicines (such as vitamins, iron)
(d) cough suppressants, expectorants and mucolytics
(e) iron preparations containing folic acid and Vitamin B12
(f) oral enzymes and digestives
(g) FDCs of cardiovascular drugs, anti-histaminic drugs, topical anti-coagulants, antacids, etc.

With regards to FDCs of anti-diabetic drugs, the AIDAN has presented the following views:

- FDCs of anti-diabetic drugs are required to be used when single drugs fail to control hyperglycemia. However, the sales pattern suggests that they are being used as initial therapy
- Combination of multiple drugs increases the risk of hypoglycemia in patients
- Some of these FDCs contain one drug to be taken after meals with the other to be taken on empty stomach
- There is no country (other than India), which has a triple-drug combination of oral anti-diabetic drugs

The AIDAN appended a letter written on behalf of the Chair ITATSA (IADVL Task Force Against Topical Steroid Abuse) of the Indian Association of Dermatologists, Venerologists and Leprologists (IADVL). The said letter objects to FDCs containing highest potency corticosteroid molecules such as clobetasol propionate and halobetasol. It states that incorporation of such high-potency steroid in FDCs results in suppression of immunity, "leading to mere symptom relief, while the infection remains untreated and spreads unabated. The patient continues to harbor the infection and spreads the disease further."

The AIDAN, in addition, submitted a list of FDCs approved by CDSCO prior to and after 2016 that it considered "irrational" and urged for a review of all the FDCs available in the Indian market.

The AIDAN representatives also pointed out that once an FDC is approved, it is marketed vigorously by the trade representatives to the pharmacists and doctors in preference to individual constituent drugs. They stated that once an FDC is marketed, the individual constituent drugs mysteriously disappear or are in short supply, entailing a compulsory use of the FDC. They stated that the individual constituent drug is covered under Drug Price Control Offer (DPCO) but not the FDC and hence the FDC is marketed and made available with greater vigor to expand profits.

AIDAN had several suggestions other than specifically pertaining to the 344+ 5 FDC under consideration. The AIDAN representatives suggested that a comprehensive medicine policy should be formulated considering that National Drug authority was proposed way back in 1994.

They stated that the appendix VI should be revised / replaced by the CDSCO 2013 guidelines. FDCs of antibiotics should have therapeutic and pharmacological rationale especially considering the misuse and resultant antimicrobial resistance. FDCs for

NSAID have high risk of ADRs. FDC of anti-diabetes and anti-hypertensive medicines should be approved, only if there is justification, and evidence of safety and efficacy and are mentioned in standard sources.

The AIDAN suggested that FDCs renewed from 1961 need to be reviewed for indication, safety, efficacy and therapeutic justification. There are some inconsistencies in the Kokate Committee report also in the 294 FDCs approved earlier in DTAB meeting. Irrational FDCs, FDCs with banned drugs should be banned. A positive list of rational FDCs be prepared. Data submitted for approval in Form 44 should be made public. Patients and prescribers should have access to unbiased information including pharmacovigilance data. Advertisements of FDCs should be monitored and violators of law be punished severely.

The AIDAN also recommended inclusion of patient interest groups on DTAB.

3.2.4 Assessment by subcommittee and co-opted experts

Information reviewed

The subcommittee reviewed information submitted by the appellants/ applicants/ AIDAN in Annexure A and D and that provided during the Hearing (thereafter also, if requested). It also reviewed relevant publically available information (salient ones listed under Bibliography).

The subcommittee specifically considered if prevalence/ incidence data pertaining to the disease/ symptom claimed to be treated or modified by the FDC was provided and if it was from India. Appellants provided letters of support from practicing doctors and informed about lack of adverse drug reaction reports, availability of the FDCs in the market, and their sales data as proof of efficacy, safety and quality.

Quality of evidence is important for the results to be valid and applicable. The subcommittee noted that the appellants usually submitted studies that lacked a reasonable standard. For example, the evidence of efficacy of an FDC/ a combination of drugs could be reasonably determined through clinical trials (and meta-analysis or systemic analyses of multiple clinical trials or research studies), which are double blind, randomized, with suitable comparator, with statistically adequate number of patients and conducted as per good clinical practice (GCP) guidelines as per schedule Y of the D & C Act. Appellants submitted as justification for the FDC, clinical trials of poor quality (not conducted as stated above) and those with favorable outcome supporting the FDC. Most of the times, the studies were conducted years back with standard criteria as mentioned above not rigorously followed. The subcommittee undertook independent literature search and found studies with opposite results. It therefore, also reviewed systematic reviews (which capture systematically all

published literature), meta-analysis (where the results of multiple studies are combined) and Cochrane reviews (unbiased analysis of evidence). It further noted that government agencies, professional organizations and WHO- publish standard treatment/ therapeutic guidelines (STGs) pertaining to different diseases, which are based on the sum total of evidence from literature. The subcommittee, relied on national guidelines or commonly used international therapeutic guidelines (for disease indication claimed by the appellant). The subcommittee also referred to standard textbooks for information on individual ingredients regarding pharmacokinetics and pharmacodynamics and adverse drug reactions.

Consideration was also given to relevant information in case reports, or websites of regulatory authorities of the UK, USA, European Union and Bangladesh, consensus statements (issued by National and International professional organizations, standard treatment guidelines by government/ professional bodies/ association), reports and recommendations of the previous committees (Kokate committee, 10 Expert committees NDAC and other relevant committees) and practical clinical experience of co-opted experts while treating patients, specifically considering patient needs.

Criteria for Assessment

Experts considered **Appendix VI of the schedule Y of the Drugs and Cosmetics Act, WHO guidelines for FDC and CDSCO 2013 guidelines for FDC** (available on website) as well as all the **information** as stated above to assess the FDC in respect of the criteria given in section 26A of the Drugs and Cosmetics Act and as mentioned specifically by the Hon. Supreme Court.

The subcommittee checked:

1. Rationale for combining the drugs used as ingredients in the FDC.
2. Relevant information on prevalence/ incidence/ epidemiological data on co-existence of diseases/ symptoms for which FDC is indicated.
3. Scientific/ animal/ clinical evidence to justify the use of FDC in the indication(s) claimed specifically if rationale and epidemiological data is not convincing.

Grounds/ reasons for attracting three factors (risk, therapeutic value, justification for inclusion of ingredients) based on information as stated above:

In compliance to directions of Hon. Supreme Court, and Section 26A of the Drugs and Cosmetics Act, the subcommittee considered (as per the WHO/ CDSCO guidelines for FDCs) if:

(a) The FDC is likely to involve any risk to human beings or animals due to:

- Undue/ excessive/ additive side-effects of two or more ingredients;

- Inclusion of components/ constituents with pharmacokinetic mismatch leading to dosing mismatch likely to cause over-dosing/ under-dosing of one or more constituents;
- Inclusion of a non-essential/ irrelevant constituent/ component leading to unnecessary exposure of patients to it and its adverse effects;
- Inclusion of a constituent with abuse potential;
- Inclusion of a constituent with narrow therapeutic index (narrow margin of safety) making dose adjustments difficult raising the possibility of undue toxicity or sub-therapeutic dose;
- In case of anti-microbial agents, irrational combination of two or more anti-microbial agents or a combination of one or more anti-microbial agent with one or more non-antimicrobial agent raising the possibility of unnecessary overuse of one agent and/ or possibility of enhancing anti-microbial resistance;
- Ill-defined patient population where the FDC is claimed to be useful, thereby leading to over-prescription of the FDC; thereby exposing the patient unnecessarily to one or more non-required constituent(s)

(b) If the said FDCs does not have the therapeutic value claimed or purported to be claimed for them:

- This was determined on the basis of review of the material (in Annexure A, including package insert, literature, evidence) submitted by the appellant, information provided during the presentation made by the appellant at the Hearing and on the basis of textbook references, published literature including clinical trials, observational studies, national and international guidelines, guidelines provided by the national or international professional organizations and expert groups and, opinion of the subject expert in the context of Indian practice. The subcommittee specifically assessed if the ingredients of the FDC are recommended to be given simultaneously in the standard treatment guidelines/ therapeutic guidelines of the indications claimed by the appellant and if there is sufficient rationale scientific/ clinical evidence while considering if the FDC has therapeutic value claimed
- If there was no reasonable evidence of efficacy for FDC or ingredients generated by the applicant or available in the literature the FDC was adjudged as lacking the therapeutic value.
- If the constituents of the FDC had antagonistic or opposing actions, making them pharmaco-dynamically inappropriate in a combination, it could be stated that their simultaneous administration through an FDC would mean decrease in the efficacy of one or more constituents and possibility of a non-response.

FDCs with such ingredients/ constituents were considered as lacking the therapeutic value.

(c) That such FDCs contain ingredients and in such quantity for which there is no therapeutic justification if there was:

- A possibility of undue/ excessive/ additive side-effects of two or more ingredients
- Inclusion of components/ constituents with opposing or antagonistic actions;
- Inclusion of components/ constituents with pharmacokinetic pharmaco-dynamic mismatch (dosing frequency mismatch) leading to over-dosing/ under-dosing of one or more constituents;
- Inclusion of a non-essential/ irrelevant constituent/ component leading to unnecessary exposure of patients to it and/ or its adverse effects;
- Inclusion of a constituent with abuse potential;
- Inclusion of a constituent with narrow therapeutic index making dose adjustments difficult raising the possibility of undue toxicity or sub-therapeutic dose;
- Irrational combination of two anti-microbial agents raising the possibility of unnecessary overuse of one agent and/ or possibility of enhancing anti-microbial resistance;
- Ill-defined patient population where the FDC is claimed to be useful, thereby leading to over-prescription of the FDC to patient population not requiring it; in turn exposing the patient unnecessarily to one or more non-required constituent(s);
- Inclusion of one or more ingredients without pharmacological action referable to the indication in the selected patient population;
- No reasonable evidence of efficacy of one or more constituents for the treatment of indication mentioned; or
- Constituents provided in inappropriate proportions leading to under-dosing/ over-dosing.

As can be seen there is an overlap in reasons for considering risk, therapeutic value and justification for ingredients. For example, if the ingredients of an FDC have dosing mismatch and if one ingredient is to be given once a day the second one twice a day and the third is to be given three times a day and if FDC is decided to be given twice a day; there will be over-dosing of one ingredient and under-dosing of another ingredient; causing risk (due to over-dosed ingredient) and reduction of therapeutic value (due to under-dosed ingredient), thus attracting all the three factors. Similarly, if

an ingredient irrelevant to the indication is present in an FDC, it would satisfy (c) as well as (b) criteria above in view of presence of an ingredient that is of no therapeutic value as well as due to the risk of adverse effects to that ingredient (with no possibility of benefit).

The subcommittee has, therefore, given the grounds/ reasons for attracting the stated factors in one column of the FDC- wise detailed report. This column should be read with the contents of the row stating the final recommendation (restriction/ regulation/ prohibition) and reasons for the said recommendations for the particular FDC.

Grounds/ reasons for recommending restriction/regulation/prohibition in larger public interest and as to why restriction regulation is not sufficient if prohibition is recommended

It should be noted that public health is an important component of larger public interest. An FDC that carries risks, has no therapeutic value and the ingredients and quantities have no therapeutic justification is injurious to health and to larger public interest.

i) An FDC was assessed not to be in public interest if its use was assessed to involve risk to human beings or animals or if it did not have the therapeutic value claimed or purported to be claimed or if the FDC contained ingredients and in such quantities that the FDC shall not have any therapeutic effect.
   If any one of the factors (risk, therapeutic value or therapeutic justification for ingredients) is attracted then as per 26A, it is to be prohibited/ restricted/ regulated in public interest.

ii) If an FDC has no therapeutic justification (therapeutic value and/ or therapeutic justification for ingredients and quantity), it would be an unnecessary and unjust burden on the pockets of poor people, result in delay in getting appropriate treatment with resulting harm to health and system getting overloaded with too many products (FDCs), is not in public interest and should be prohibited. Restriction/regulation is not sufficient.

iii) If an FDC is not in conformity to national treatment guidelines/ international treatment guidelines followed in the country/ WHO guidelines, it is not in general public interest and hence needs to be prohibited. Restriction and regulation is not sufficient.

iv) If the drug is not in conformity to the prescribed standards of safety, efficacy, quality, it is likely to be injurious to health and needs to be prohibited, restriction or regulation is not sufficient.

v) If the drug has risks (side effects, abuse potential) outweighing benefits and safer alternatives are available, in public interest it should be prohibited. Restriction/ regulation is not sufficient.

vi) Only when an FDC is rational and passes all the considerations mentioned in (a), (b) and (c) above (including pharmacodynamics coherence, matching dosing schedule, absence of excessive adverse effects, reasonable proof of efficacy and safety, presence of only essential ingredients and that too in acceptable quantities and proportions, and as per treatment guidelines); but there is a need to restrict or regulate its use in larger public interest, can the regulation or restriction be considered as an option. A few examples where restriction/ regulation could be considered are cited below: Therapy of a condition requires a phasic or step-wise approach (if one drug in maximum tolerated dose is not adequate then second drug is added) and non-adherence to such approach is irrational and not in patients' interest. In such a situation, a restriction can be advised to use in a specific population. For example, FDCs containing 3 different oral hypoglycemic agents (OHAs) for the treatment of type-2- Diabetes mellitus (T2DM) restriction for use "when diet, exercise, monotherapy and dual therapy do not achieve adequate glycemic control" is a reasonable option. A particular FDC has certain harmful effects in a particular population (say, children). If the FDC is otherwise rational, its use restricted to the adult population can be considered.

Comments on information received from the appellant

Of the 349 FDCs, 812 representations were received for 184 FDCs. With regards to hearing, 467 companies came up for hearing for 156 FDCs and were given hearing.

On perusal of information, data and references submitted by the appellants and hearing given to various appellants, the following general observations were made:

Quality of Information Submitted:

Most Appellants had not generated efficacy and/ or safety data for their own FDC/ combination. They could not provide any supportive data for the combination from literature and the evidence provided was not relevant to the FDC under consideration. Several of the published studies provided in support of FDC were poorly designed (refer above for criteria for quality of evidence) or their full-texts were not made available. They were at times in foreign languages (without translation).

Table 3:

Examples of FDCs, wherein irrelevant or poor quality evidence was provided for supporting the corresponding FDC

Sr. No.	S.O. No.	Evidence Provided	Comment
1	731	Coudreuse JM, et al. Effect of a plaster containing DHEP and heparin in acute ankle sprains with oedema: a randomized, double-blind, placebo-controlled clinical study. Current Medical Research and Opinion 2010; 26:2221-8	Publication not relevant, as the FDC pertained to a gel preparation
2	776	Mero WMS, et al. Microorganisms and viruses causing diarrhea in infants and primary school children and their relation with age and sex in Zakho city, Kurdistan Region, Iraq. International Journal of Research in Medical Sciences 2015; 3:3266-73	Article not relevant as it provided data regarding prevalence of mixed infection in Iraq, when data regarding prevalence in India was required.
3	736	Eremenko AA, et al. Combined analgesia in early periods after cardiosurgical operations. Anesteziol Reanimatol 2006; (6):47-50	Only Abstract submitted
4	737	Pant KK, et al. PARFLEX- a very useful drug for management of surgical pain. J Indian Med Assoc 2008;106:409-11	Only Abstract submitted
5	740	Birring SS, et al. Rococo Study: a real-world evaluation of an over-the-counter medicine in acute cough (a multicenter, randomised, controlled study) BMJ Open 2017; 7:e014112	Poor quality evidence submitted (primary efficacy endpoint not achieved; no blinding; constituents of the two arms of the study irrelevant to the FDC
7	781	Could not be ascertained	Full-text article written in the Russian language submitted without translation

Safety:

The appellants informed that FDC was being marketed in the country for several years, there have been no reports of adverse reactions from the prescribers or the consumers. Prescribers were generally happy with the FDCs and annual sales were good. However, absence of information regarding adverse events cannot be equated with absence of adverse events/ side-effects. Authentic information about adverse effects can be generated through active surveillance. Given the absence of active pharmacovigilance system in place, it is difficult to equate lack of reports with actual safety of an FDC.

Indications:

Some appellants did not provide a "product insert/ package insert" as a part of initial or subsequent submission. The information provided regarding indications was at times unclear and included disorders which were not concerned with the FDC. Many appellants had not provided indications in Annexure A/ Package Insert document/ during presentation. The subcommittee noted that the appellants were not able to state the approved indications for the FDC they were manufacturing or marketing. A few appellants provided a photocopy of the approval letter provided by the respective State Licensing Authority (SLA) and it was noted that the document submitted as an "approval letter" did not specify the indication for which the FDC was approved.. Appellants requested the subcommittee to allow them to change the indications during (or at times even after) the presentation, probably unaware that 'Addition and/ or change of indications' requires processing of application as a "new drug".

Table 4:

Examples of FDCs wherein discrepancies were noted related to indication

No.	S. O. No.	Constituents	Comment
1	740	Ammonium chloride, Sodium citrate, chlorpheniramine, menthol in syrup	The indication mentioned in Annexure A was "broad spectrum antibiotic'; which is absurd
2	868	Paracetamol, loratidine, dextromethorphan, pseudoephedrine, caffeine	The indication mentioned in Annexure A was "Chronic idiopathic urticarial", which is irrelevant
3	894	Chlorpheniramine, phenylephrine, menthol, dextromethorphan	Package insert not submitted

4	909	Chlorpheniramine maleate, codeine	Indication stated in Annexure A stated as "dry cough", which does not match with the indication written in the package insert: "dry, irritating, disturbing cough in allergic or infective conditions of respiratory passage, example, sinusitis, hay fever, pharyngitis, acute bronchitis, tuberculosis"
5	770	Ciprofloxacin USP 250mg+ Phenazo-pyridine 200 mg	The company requested to change the indication from "Urinary tract infection" to "short course 2-day therapy in uncomplicated Urinary tract infection like cystitis or urethritis in females"
6	802	Glimepiride+ Pioglitazone+ Metformin	One of the appellants did not mention "indication" in Appendix A
7	805	Pioglitazone+ Metformin	One of the Appellants mentioned that indication will be submitted "in due course" in Appendix A

Standard Therapeutic Guidelines:

Most appellants could not provide treatment guidelines in support of their FDC/ combination used in the FDC.

Over the counter (OTC) drugs in developed countries :

Some appellants claimed that the composition of the FDC manufactured and/or marketed by them was same as or similar to an over-the-counter (OTC) FDC marketed in a developed country with advanced regulatory authority. However, the subcommittee noted that in many instances, the OTC products were similar but not identical to the FDC in the Indian market which differed from their FDC in terms of number of constituents, exact composition or dosage schedule.

Where the FDC are identical, one needs to consider the approval system in the USA vis-à-vis the criteria applied by the subcommittee as per the order of the Hon. Supreme Court.

The US FDA system is not robust, is evolving and relies on a monograph system, and not the FDC *per se*.

Table 5:

Differences in the ingredients / indications of FDCs in India and "similar" OTC drugs marketed in a developed country

S. No.	S. O. No.	Ingredients of FDC marketed/ sought to be marketed in India	Referenced OTC product marketed in a developed country
1	950	Caffeine, paracetamol, phenylephrine, chlorpheniramine	Paracetamol, phenylephrine, chlorpheniramine

Products marketed as OTC in USA may contain effective doses of some ingredients and sub-therapeutic doses of others. There may be differing duration of action among the ingredients and there is a possibility that clinician or patient is unaware of the presence of certain active ingredients.

Ingredients :

Several FDCs had constituents that were required to be given at different frequencies during the day. The applicants could not provide a justification for the same.

Table 6:

Examples of FDCs where the ingredients with different dosing schedules were combined in an FDC

No.	S.O. No.	Constituents	Comment
1	971	N-Acetyl Cysteine, Ambroxol, Phenylephrine and Levocetirizine	Levocetirizine is given once a day while ambroxol is to be given three times a day
2	871	Salbutamol, Cetirizine and Ambroxol	Cetirizine is given once a day while salbutamol is given 3- 4 times a day
3	705	Aceclofenac, Paracetamol and Rabeprazole	Aceclofenac is given twice a day, rabeprazole is given once a day, while paracetamol is given three- four times a day

Many FDCs had many constituents. In some FDCs, the constituents were irrelevant to the indication stated. The appellants could not provide justification in this regard.

Table 7:

Examples of FDCs where one/ more ingredients were irrelevant to the indication mentioned

No.	S.O. No.	Constituents	Comment
1	813	Metformin, Glimepiride and methcobalamine	The only indication mentioned was "For the treatment of diabetes". Methcobalamine has no role in the treatment of diabetes.
2	772	Cetirizine Dihydrochloride + Diethyl Carbamazine	The indication was mentioned as "Tropical Pulmonary Eosinophilia and Asthma". Neither of the drugs has any role in the management of asthma. Cetirizine has no role in the management of tropical pulmonary eosinophilia
3	752	Azithromycin and Cefixime	One of the indications for the FDC was stated to be "P. falciparum malaria with other anti-malarial drugs

Pre-1988 approved

It is pertinent to mention here that the combination of two or more drugs i.e. FDC combined for the first time fall under the definition of New Drug. The requirements for import, manufacture for sale and sale of New drugs including FDCs was introduced in the Drugs and Cosmetics Rules, 1945 vide GSR No. 944E dated 21.9.1988 by introducing Rule 122A, 122B, 122D and Schedule Y.

As per the decision taken in the Action Taken Note on the 59th report, DCG(I) vide letter no. 4-01/2013-DC (Misc13-PSC) dated 15.1.2013 had requested the Drug controllers of all the states and union territories to ask the concerned manufacturers in their respective State or union territory to provide evidence for the safety and efficacy of such FDCs which are licensed by SLAs without approval of DCGI within a period of 18 months, failing which such FDCs would be considered for being prohibited for manufacture and marketing in the country.

The DCG(I) vide letter dated 05.06.2014 further clarified that requirement of proving safety and efficacy as mentioned above in not applicable for such FDCs which are licensed prior to 21.09.1988.

Several appellants claimed that they had license prior to 1988. However, many of them were unable to provide any documentary proof of them having license dated prior to 1988. In many instances, the composition of FDCs when the license was granted (pre-1988) was different from the currently manufactured FDC. All the claimants were informed that the subcommittee is examining even those FDCs who were granted license purportedly before 1988, on the explicit orders of the DTAB as per minutes of the meeting. Lawyers representing one appellant objected and submitted their objection to the subcommittee.

CDSCO approved similar FDCs

Several appellants claimed that FDCs with "similar" constituents were already approved by the DCGI. The subcommittee has reviewed and assessed every FDC, as per the criteria provided by the Supreme Court, based the evidence presented before it by the appellants and the evidence that it could gather with the help of experts, thus taking into account factors that CDSCO might not have considered

4. Recommendations for each FDC/ appellant with grounds/ reasons for attracting three factors, and grounds/ reasons for recommendation

4.1 Explaining the layout of Table 8 that gives the FDC wise recommendations

Table 8 provides a summary of information submitted by each appellant about composition of the FDC, indications as stated by them in Annexure A and in package insert and marketing status.

The next column provides grounds/reasons for attracting one of the three factors (risks, therapeutic value, justification for ingredients in the FDCs) based on the documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analyzed.

As stated above, there is an overlap in reasons for considering risk, therapeutic value and justification for ingredients. The subcommittee has, therefore, given the grounds/ reasons for attracting the stated three factors in one column.

As stated above it has looked at clinical/scientific evidence and considered it to be not sound/ convincing if it did not fulfill clinical trial criteria stated above or did not follow usual research methodology.

Relevant salient literature perused is provided in Bibliography .It was not possible to give as references as there were several publications for same FDC and on the other hand same publication was applicable to several FDCs .

The recommendations and reasons for recommendation are given for each FDC in a row after the columns that provide information for each FDC and each appellant.

The contents of the row stating the final recommendation (restriction/ regulation/ prohibition) and reasons for the said recommendations for the particular FDC should be read with the column giving reasons for attracting the three factors.

The grounds/ reasons for recommending restriction/regulation/prohibition in larger public interest and as to why restriction regulation is not sufficient if prohibition is recommended have been stated above in section 3.2.4 assessment

(It is important to mention that some petitioners/ appellants did not submit information under Annexure A as sought by the subcommittee, however appeared for hearing before the subcommittee. These petitioners were also heard by the subcommittee)

4.2 FDC wise Recommendations in Table 8 (on next page)

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 705(E)	Aceclofenac + Paracetamol + Rabeprazole	Macleods	Aceclofenac IP 100mg+ Paracetamol IP 325mg+ Rabeprazole Sodium IP 10mg (ER) hard gelatin capsule	Is used for the relief of pain and inflammation in rheumatoid arthritis, osteoarthritis and ankylosing spondylitis.	i. Same as per Annexure A ii. Not approved	1. Pharmacokinetic mismatch: Aceclofenac is given two times a day; Rabeprazole is administered once a day and Paracetamol four times a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 705(E)	Aceclofenac + Paracetamol + Rabeprazole	Wockhardt	Aceclofenac IP 100mg + Paracetamol IP 325mg+ Rabeprazole Sodium IP 10mg (ER) film coated tablet	Is used for • The relief of pain and inflammation associated with rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. • For acute painful conditions such as dental pain, post operative pain, dysmenorrhoea, musculoskeletal trauma(sprains, strains etc) acute lumbago , pain associated with pharyngitis.	i. Same as per Annexure A ii. Not approved	1. Pharmacokinetic mismatch:Aceclofenac is given two times a day; Rabeprazole is administered once a day and Paracetamol four times a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 705(E)	Aceclofenac + Paracetamol + Rabeprazole	Akums Drugs	Aceclofenac IP 100mg+ Paracetmol IP 325mg+ Rabeprazole (Enteric coated form) 10mg hard gelatin capsules	Is used for the treatment of acute pain management of any etiology and decrease the risk of developing gastric ulcers.	i. Same as per Annexure A ii. Not approved	1. Pharmacokinetic mismatch:Aceclofenac is given two times a day; Rabeprazole is administered once a day and Paracetamol four times a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 705(E)	Aceclofenac + Paracetamol + Rabeprazole	Akums Drugs	Aceclofenac IP 100 mg + Paracetamol IP 325 mg + Rabeprazole Sodium IP 10 mg (in enteric coated form) film coated tablet	Is used for the treatment of acute pain management of any etiology and decrease the risk of developing gastric ulcers.	i. Same as per Annexure A ii. Not approved	1. Pharmacokinetic mismatch: Aceclofenac is given two times a day; Rabeprazole is administered once a day and Paracetamol four times a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 705(E)	Aceclofenac + Paracetamol + Rabeprazole	Mascot Healthcare	Aceclofenac IP 100mg+ Paracetmol IP 325mg+ Rabeprazole (Enteric coated form) 10mg film coated tablets	used in the treatment of Pain & inflammation	i. Pack insert mentions indication for individual ingredient and not for FDC. ii. Not submitted	1. Pharmacokinetic mismatch: Aceclofenac is given two times a day; Rabeprazole is administered once a day and Paracetamol four times a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 705(E)	Aceclofenac + Paracetamol + Rabeprazole	Jenburkt Pharmaceuticals	Aceclofenac IP 100mg+ Paracetamol IP 325mg+ Rabeprazole Sodium IP (as enteric coated tablet) 10mg hard gelatin capsule	used in the treatment of acute pain associated with inflammatory conditions such as lumbago, acute postoperative pain, Acute flare-ups of OA.	i. Same as per Annexure A ii. Not approved	1. Pharmacokinetic mismatch: Aceclofenac is given two times a day; Rabeprazole is administered once a day and Paracetamol four times a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
1	S.O. 705(E)	Aceclofenac + Paracetamol + Rabeprazole	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 706(E)	Nimesulide + Diclofenac	Emcure Pharmaceuticals	Nimesulide BP 100mg+ Diclofenac Sodium IP 50mg soft gelatin capsule	It can be used for symptomatic treatment only, in adults symptomatic treatment of acute painful conditions. • Resulting for trauma ,. Including fracture , low back pain, sprains , strains , dislocations, orthopaedic , dental and minor surgery. • Periarthritis (for example frozen shoulder), tendinitis, tenosynovitis, bursitis, symptomatic treatment of painful osteoarthritis.	i. Same as per Annexure A ii. Not approved	1. Nimesulide in combination has potential of misuse and safety concern. It's use in children below 12 years is already banned in India and it's use is limited to 15 days in adults in Europe. 2. Pharmacodynamically inappropriate FDC as both have similar mechanism of action (both drugs acting on the same enzyme). However, adverse effects of the two drugs (such as Gastrointestinal ulceration, nephrotoxicity and hepatotoxicity) add up. Thus, combining two NSAIDs may not improve the efficacy of treatment but may increase the risk. 3. Further, Diclofenac poses specific risk to animals (Vultures). 4. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 706(E)	Nimesulide + Diclofenac	Elnova Pharma	Nimesulide BP 100mg+ Diclofenac Sodium IP 50mg soft gelatin capsule	Non steroidal anti-inflammatory drug	i. Not Submitted ii. Not submitted	1. Nimesulide in combination has potential of misuse and safety concern. It's use in children below 12 years is already banned in India and it's use is limited to 15 days in adults in Europe. 2.Pharmacodynamically irrational FDC as both have similar mechanism of action (both drugs acting on the same enzyme). However, adverse effects of the two drugs (such as Gastrointestinal ulceration and hepatotoxicity) add up. Thus, combining two NSAIDs may not improve the efficacy of treatment but may increase the risk. 3. Further, Diclofenac poses specific risk to animals (Vultures). The Subcommittee perused and deliberated on the details submitted and presentation given by the appellant during the Hearing. There is no convincing scientific/ clinical evidence/ justification submitted by the company for the FDC.
	S.O. 706(E)	Nimesulide + Diclofenac	Akums Drugs	Nimesulide BP 100mg+ Diclofenac Sodium IP 50mg soft gelatin capsule	For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.	i. Same as per Annexure A ii. Not approved	1. Nimesulide in combination has potential of misuse and safety concern. It's use in children below 12 years is already banned in India and it's use is limited to 15 days in adults in Europe. 2.Pharmacodynamically irrational FDC as both have similar mechanism of action (both drugs acting on the same enzyme). However, adverse effects of the two drugs (such as Gastrointestinal ulceration and hepatotoxicity) add up. Thus, combining two NSAIDs may not improve the efficacy of treatment but may increase the risk. 3. Further, Diclofenac poses specific risk to animals (Vultures). The Subcommittee perused and deliberated on the details submitted and presentation given by the appellant during the Hearing. There is no convincing scientific/ clinical evidence/ justification submitted by the company for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 706(E)	Nimesulide + Diclofenac	Horizon Bioceuticals	Nimesulide BP 100mg+ Diclofenac Potassium IP 50mg uncoated tablet	Anti-inflammatory, Analgesic and antipyretic	i. Same as per Annexure A ii. Not submitted	1. Nimesulide in combination has potential of misuse and safety concern. It's use in children below 12 years is already banned in India and it's use is limited to 15 days in adults in Europe. 2.Pharmacodynamically irrational FDC as both have similar mechanism of action (both drugs acting on the same enzyme). However, adverse effects of the two drugs (such as Gastrointestinal ulceration and hepatotoxicity) add up. Thus, combining two NSAIDs may not improve the efficacy of treatment but may increase the risk. 3. Further, Diclofenac poses specific risk to animals (Vultures). The Subcommittee perused and deliberated on the details submitted and presentation given by the appellant during the Hearing. There is no convincing scientific/ clinical evidence/ justification submitted by the company for the FDC.
2	S.O. 706(E)	Nimesulide + Diclofenac	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 707(E)	Nimesulide+ Cetirizine+ Caffeine	Akums Drugs	Nimesulide BP 100mg+ Cetirizine HCl IP 5mg+ Caffeine (Anhydrous) IP 30mg uncoated bilayered tablet	The treatment of fever and symptomatic acute pain associated with cold, nasal congestion in adults.	i) Indication same as Annexure-A ii) Not Available	The Subcommittee noted that FDC of Nimesulide+ Levocetirizine was deliberated by SEC (Pulmonary) in its meeting held on 24.09.2014: "The SEC committee examined and opined that the FDC is not rational as Levocetirizine is anti-histaminic whereas Nimesulide is an antipyretic, analgesic and the combination is likely to be misused/overused in situations where single drug is required. Further this FDC is not approved anywhere in the world. Hence the SEC committee did not recommend for its continued marketing in the country." The DTAB Subcommittee concured with the opinion of SEC and and opined that the same is applicable for Cetirizine also. Additionally, the subcommittee noted that: 1. There is pharmacokinetic mismatch: Nimesulide is given twice a day whereas Cetirizine is given once a day. 2. Rationale for including Caffeine in the FDC as provided by the company is not appropriate. 3. Nimesulide is prohibited for use in children below 12 years. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 707(E)	Nimesulide+ Cetirizine+ Caffeine	Horizon Bioceuticals	Nimesulide BP 100mg+ Cetirizine HCl IP 5mg+ Caffeine (Anhydrous) IP 30mg per 5mL suspension	Anti-inflammatory, analgesic, antihistaminic& CNS stimulant.	i) Indication same as Annexure-A ii) Not Approved	The Subcommittee noted that FDC of Nimesulide+ Levocetirizine was deliberated by SEC (Pulmonary) in its meeting held on 24.09.2014: "The SEC committee examined and opined that the FDC is not rational as Levocetirizine is anti-histaminic whereas Nimesulide is an antipyretic, analgesic and the combination is likely to be misused/overused in situations where single drug is required. Further this FDC is not approved anywhere in the world. Hence the SEC committee did not recommend for its continued marketing in the country." The DTAB Subcommittee concured with the opinion of SEC and opined that the same is applicable for Cetirizine also. Additionally, the subcommittee noted that: 1. There is pharmacokinetic mismatch: Nimesulide is given twice a day whereas Cetirizine is given once a day. 2. Rationale for including Caffeine in the FDC as provided by the company is not appropriate. 3. Nimesulide is prohibited for use in children below 12 years. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
3	S.O. 707(E)	Nimesulide+ Cetirizine+ Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 708(E)	Nimesulide+ Tizanidine	Unison	Nimesulide BP 100mg +Tizanidine HCl IP eq. To Tizanidine 2mg uncoated tablet	It is indicated to reduce Post operative oedema and restores micro-circulation at the site of graft rejection with respiratory medicines to break down comlex sputum molecules in smaller peptides. It reduces viscosity of secretion helps in better antibiotic penetration to enable control over stubborn infections.	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Trauma Surgery: In sports injuries, sprains, laceration, fractures, dislocation and osteoarthritis etc. It reduces inflammation and pain thus helps faster healing and repair. Surgery: Reduces Post Operative Edema at injection sites. Reduces internal tissue edema and inflammation caused at post-operative handling. Reduction in edema reduces chances of rupture at tissue site as well as risk of graft rejection along with reduction in pain . Plastic Surgery: Reduces Post Operative Edema and restores micro-circulation at the site of graft rejection. Respiratory Medicine: Breaks down complex sputum molecules in smaller peptides with lower viscosity, helping in expectorating them more easily. Reduced viscosity of secretion helps in better antibiotic penetration to enable control over stubborn infections like bronchitis, lung abscess and bronchectasis. Nimesulide helps in controlling pain and inflammation. Infections: Mucolytic activity in sinuses, ear cavities and anti-inflammatory activity in upper	1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 2. Tizanidine has been linked to rare instances of acute liver injury, a few of which have been fatal. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 4. In view of the various restrictions on use of Nimesulide and the adverse effects of the two drugs individually, this FDC is not justified. 5. The indications mentioned by the appellant in Annexure A are irrelevant for this FDC. There is no convincing scientific/ clinical evidence/ justification for the FDC.

Contd...

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
						respiratory tract organs help in faster resolution, better antibiotic bioavailability and faster cure rates. Dermatology: Used in acute painful inflamed dermatoses. Dentistry: Helps better control over dental infections and inflammation. Obstetrics &Gyneacology: The anti-inflammatory activity helps in resolution of post- partum haematomas, breast engorgements and pregnancy-related thrombophlebitis. ii. not submitted	
	S.O. 708(E)	Nimesulide+ Tizanidine	Akums Drugs	Nimesulide BP 100mg+Tizanidine HCL IP eq. to Tianidine 2mg uncoated dispersible tablet	Muscle spasm such as fractures, spondylitis, lumbago (lower back &buttock pain), rheumatoid arthritis, postoperative trauma, sports injuries.	i. Same as per Annexure A ii. Not approved	1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 2. Tizanidine has been linked to rare instances of acute liver injury, a few of which have been fatal. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 4. In view of the various restrictions on use of Nimesulide and the adverse effects of the two drugs individually, this FDC is not justified. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 708(E)	Nimesulide+ Tizanidine	Dr. Reddy's Laboratories	Nimesulide BP 100mg+Tizanidine HCl IP eq. to Tizanidine 2mg uncoated tablets	Is used in the treatment of acute low back pain in adult patients only.	i. same as per Annexure A ii. Not approved	1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 2. Tizanidine has been linked to rare instances of acute liver injury, a few of which have been fatal. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 4. In view of the various restrictions on use of Nimesulide and the adverse effects of the two drugs individually, this FDC is not justified. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 708(E)	Nimesulide+ Tizanidine	DM Pharma	Nimesulide BP 100mg+Tizanidine HCl IP Eq. to Tizanidine 2mg tablet	Muscle spasm such as fractures, sprains, spondylitis, lower back pain, rheumatoid arthritis, postoperative trauma, sports injuries	i. Same as per Annexure A ii. Not approved	1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 2. Tizanidine has been linked to rare instances of acute liver injury, a few of which have been fatal. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 4. In view of the various restrictions on use of Nimesulide and the adverse effects of the two drugs individually, this FDC is not justified. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 708(E)	Nimesulide+ Tizanidine	Meridian Medicare	Nimesulide BP 100mg+Tizanidine HCl IP Eq. to Tizanidine 2mg tablet	Treatment and management of moderate inflammation and pain symptoms associated with sports injuries, spondylitis, post-operative trauma, sprains and lumbago and it can reduce spasticity and alleviate muscular sprains.	i. Not Submitted ii. Not submitted	1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 2. Tizanidine has been linked to rare instances of acute liver injury, a few of which have been fatal. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 4. In view of the various restrictions on use of Nimesulide and the adverse effects of the two drugs individually, this FDC is not justified. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 708(E)	Nimesulide+ Tizanidine	Wings Pharmaceuticals Pvt. Ltd.	Nimesulide BP 100mg+Tizanidine HCl IP Eq. to Tizanidine 2mg uncoated tablet	Analgesic and Muscle relaxant	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Relieve pain and relax the muscles. Trauma surgery, surgery, plastic surgery: Reduce post operative edema at injection sites. Reduce internal tissue edema and inflammation caused at post operative handling. Rejection in edema reduces chances of rupture at tissue site as well as risk of graft rejection along with reduction in pain. ii. not submitted	1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 2. Tizanidine has been linked to rare instances of acute liver injury, a few of which have been fatal. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 4. In view of the various restrictions on use of Nimesulide and the adverse effects of the two drugs individually, this FDC is not justified. There is no convincing scientific/ clinical evidence/ justification for the FDC.
4	S.O. 708(E)	Nimesulide+ Tizanidine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 709(E)	Paracetamol+ Cetirizine+ Caffeine	Akums Drugs	Paracetamol IP 325mg+ Cetirizine HCl IP 5mg+ Caffeine (Anhydrous) IP 15mg uncoated tablet	For the temporary relief from fever and pains associated with allergy symptoms such as running nose, sneezing, watery eyes etc.	i) Indications mentioned in package insert not same as Annexure A. Indications metioned in package insert are: This medication is temporary relief of fever, minor aches, and pains. Its used to treat cold or allergy symptoms such as sneezing, itching, watery eyes or running nose. ii) Not Approved	1. Pharmacokinetic incompatibility as paracetamol is given three to four times a day while Cetirizine is given once a day. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect claimed by the appellant. 3. This combination is not as per standard therapeutic guideline. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
5	S.O. 709(E)	Paracetamol+ Cetirizine+ Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 710(E)	Diclofenac+ Tramadol+ Chlorzoxazone	Mascot Healthcare	Diclofenac Sodium IP 50mg+ Tramadol HCl IP 37.5mg+ Chlorzoxazone USP 250mg filmcoated tablet	Pain & Inflammation, Low back pain, painful skeletal muscle spasms.	i. Indications not mentioned in package insert for the FDC specifically. ii. Not approved	1. Presence of Tramadol in FDC confers abuse liability. 2. Tramadol and Chlorzoxazone both are sedative. The combination may lead to excessive sedation. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and risk of ADRs. There is no convincing scientific/ clinical evidence/ justification for the FDC.
6	S.O. 710(E)	Diclofenac+ Tramadol+ Chlorzoxazone	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **The FDC may involve risk to human beings and there is no therapeutic justification for the FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 711(E)	Dicyclomine + Paracetamol + Domperidone	-	-	-	-	1. Pharmacodynamically incompatible as each ingredient has different therapeutic uses and adding them together does not appear to provide any additive or synergistic effect for any given indication. Use of this FDC will lead to misuse and unnecessary ADR burden. 2. Dicyclomine is an anticholinergic and anti-spasmodic drug and tends to inhibit intestinal movements, while domperidone is a pro-kinetic agent. Used in combination they are likely to antagonize each other's actions. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects There is no convincing scientific/ clinical evidence/ justification for the FDC.
7	S.O. 711(E)	Dicyclomine + Paracetamol + Domperidone	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 712(E)	Nimesulide +Paracetamol dispesible tablets	Akums Drugs	Nimesulide BP 100mg+Paracetamol IP 325mg uncoated dispersible tablet	Blocking the production of prostaglandins thereby relieving pain and inflammation.	i. Same as per Annexure A ii. Not approved	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the Subcommittee noted that FDC of Nimesulide 100mg + Paracetamol 325mg uncoated tablet is appoved by DCGI and not the dispersible tablet. During presentation, firm claimed the FDC to have been approved before 1988 as per the IMS data . However, the company did not submit any evidence for the same. As per the CDSCO website (URL: http://www.cdsco.nic.in/writereaddata/1991-2000.pdf) Nimesulide single ingredient formulations were approved in 1995. Subcommittee comments are as follows: 1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. Nimesulide in combination as a dispersible dosage form has strong potential of misuse in children. 2. Nimesulide and Paracetamol both have hepatotoxic potential. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. 4. There is a dosing mismatch: Nimesulide is given once or twice a day while Paracetamol is given four times a day. 5. Specific indication not mentioned and no specific patient population has been identified for this FDC by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 712(E)	Nimesulide + Paracetamol dispesible tablet	Franklin Laboratories	Nimesulide BP 100mg+Paracetamol IP 325mg uncoated tablet	Not submitted	i. Not Submitted ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the Subcommittee noted that FDC of Nimesulide 100mg + Paracetamol 325mg uncoated tablet is appoved by DCGI and not the dispersible tablet. As per the CDSCO website (URL: http://www.cdsco.nic.in/writereaddata/1991-2000.pdf) Nimesulide single ingredient formulations were approved in 1995. Subcommittee comments are as follows: 1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. Nimesulide in combination as a dispersible dosage form has strong potential of misuse in children. 2. Nimesulide and Paracetamol both have hepatotoxic potential. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. 4. There is a dosing mismatch: Nimesulide is given once or twice a day while Paracetamol is given four times a day. There is no convincing scientific/ clinical evidence/ justification for the FDC.
8	S.O. 712(E)	Nimesulide + Paracetamol dispesible tablet	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: The Subcommittee is of the opinion that:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 713(E)	Paracetamol+ Phenylephrine+ Caffeine	Remidex Pharma/ GSK	Paracetamol IP 500mg+ Phenylephrine HCl IP 10mg+ Caffeine Anhydrous IP 32mg	For effective relief from nasal congestion, stuffy nose, headache, bodyache and sore throat pain	i) Indications mentioned in Annxeure-A is different form the package insert. Package insert includes: It is decongestant , anlgesic and anti pyretic tablet. ii) Not Approved	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect claimed by the appellant. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 713(E)	Paracetamol+ Phenylephrine+ Caffeine	Reckitt Benckiser	Paracetamol IP 500mg+ Phenylephrine HCl IP 10mg+ Caffeine Anhydrous IP 32mg uncoated tablet	Rhinosinusitis, Cold, Flu	i)Same as annexure-A ii) i)Marketed : Marketed worldwide, available in UK, Singapore, Vietnam, Spain, Malaysia, Croatia, Slovenia, Poland, Germany and New Zealand ii)Approved : UK, Singapore, Vietnam, Spain, Malaysia, Croatia, Slovenia, Poland, Germany and New Zealand iii)Approved as IND : NA iv)Withdrawn, if any, with reasons : Not known	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect claimed by the appellant. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 713(E)	Paracetamol+ Phenylephrine+ Caffeine	Akums Drugs	Paracetamol IP 500mg/325mg+ Phenylephrine HCl IP 10mg/5mg+ Caffeine Anhydrous IP 32mg/30mg uncoated tablet	Rhinosinusitis, Cold, Flu	Indication same as Annexure-A i) Not Available	The Ssubcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect claimed by the appellant. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 713(E)	Paracetamol+ Phenylephrine+ Caffeine	Proctor & Gamble Hygiene	Paracetamol IP 500mg+ Caffeine IP 32mg+ Phenylephrine HCL IP 10mg uncoated tablets	Vicks action 500 extra effectively relieves cold and flu symptoms (Headache, body ache, sore throat pain, blocked nose and associated fever and lethargy).	i)Indication same as Annexure-A ii) i) Marketed :UK, Colombia, Egypt, hungary, mexico, south Africa, Nigeria & vietnam ii) Approved :UK, Colombia, Egypt, hungary, mexico, south Africa, Nigeria & vietnam iii) Approved as IND : iv) withdrawn, if any, with reasons :	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect claimed by the appellant. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 713(E)	Paracetamol+ Phenylephrine+ Caffeine	Akums Drugs	Paracetamol IP 500mg/500mg+ Phenylephrine HCl IP 10mg/10mg+ Caffeine Anhydrous IP 32mg/2mg tablet	Common Cold and Flu	i) Indications mentioned in package insert are: common Cold and Flu symptoms ii) Not Available	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect claimed by the appellant. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
9	S.O. 713(E)	Paracetamol+ Phenylephrine+ Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 714(E)	Diclofenac+ Tramadol+ Paracetamol	Combitic Global	Diclofenac Sodium BP 50mg+ Tramadol HCL BP 25mg+ Paracetamol BP 500mg uncoated tablet	Analgesic, Anti-pyretic & Anti inflammatory	i. Not Submitted ii. Not submitted	1. Presence of Tramadol in FDC confers abuse liability. 2. There is no clinical evidence/ justification to combine these three drugs in this FDC. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 714(E)	Diclofenac+ Tramadol+ Paracetamol	Combitic Global	Diclofenac Sodium BP 50mg+ Tramadol HCL BP 25mg+ Paracetamol BP 350mg uncoated tablet	Analgesic, Anti-pyretic & Anti inflammatory	i. Not Submitted ii. Not submitted	1. Presence of Tramadol in FDC confers abuse liability. 2. There is no clinical evidence/ justification to combine these three drugs in this FDC. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 714(E)	Diclofenac+ Tramadol+ Paracetamol	Combitic Global	Diclofenac Sodium BP 50mg+ Tramadol HCL BP 25mg+ Paracetamol BP 350mg film coated tablet	Analgesic, Anti-pyretic & Anti inflammatory	i. Not Submitted ii. Not submitted	1. Presence of Tramadol in FDC confers abuse liability. 2. There is no clinical evidence/ justification to combine these three drugs in this FDC. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
10	S.O. 714(E)	Diclofenac+ Tramadol+ Paracetamol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings and animals.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 715(E)	Diclofenac + Paracetamol + Chlorzoxazone + Famotidine	Skan Research	Diclofenac potassium 50mg (EC)+ Paracetamol 325mg+ Chlorzoxazone 250mg+ Famotidine 20mg uncoated tablet	Symptomatic treatment of acute and chronic rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, Juvenile arthritis, Symptomatic relief of postoperative pain (including that associated orthopaedic, gynaecologic and oral surgery) and orthopaedic pain (including musculoskeletal sprains and traumatic joint distortions), temporary analgesia in the treatment of mild to moderate pain, pain associated with migraine headache, pain associated with osteoarthritis, fever, relief of discomfort associated with acute painful musculoskeletal conditions	i) Same as Annexure A ii) Not submitted	1. The indications mentioned by the appellant are too broad and non specific and may lead to misuse. 2. Pharmacokinetically inappropriate as each ingredient has different dosing schedule/dosing requirement (Diclofenac 2-3 times a day, Paracetamol 4-6 hourly for fever and pain SOS, Chlorzoxazone 3-4 times a day and Famotidine once or twice daily). 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 715(E)	Diclofenac + Paracetamol + Chlorzoxazone + Famotidine	Horizon Bioceuticals	Diclofenac potassium 50mg (EC)+ Paracetamol 325mg+ Chlorzoxazone 250mg+ Famotidine 10mg uncoated tablet	Anti inflammatory, analgesic and muscle relaxant	i) Same as Annexure A ii) Not submitted	1. The indications mentioned by the appellant are too broad and non specific and may lead to misuse. 2. Pharmacokinetically inappropriate as each ingredient has different dosing schedule/dosing requirement (Diclofenac 2-3 times a day, Paracetamol 4-6 hourly for fever and pain SOS, Chlorzoxazone 3-4 times a day and Famotidine once or twice daily). 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects There is no convincing scientific/ clinical evidence/ justification for the FDC.
11	S.O. 715(E)	Diclofenac + Paracetamol + Chlorzoxazone + Famotidine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 716(E)	Naproxen+ Paracetamol	Macsur	Naproxen IP 300mg/550mg+Paracetamol IP 325mg/325mg film coated tablet	Is used as anti inflammatory and analgesic.	i. Same as per Annexure A ii. :submitted i) Marketed :Mexico, Peru, Ecuador, Costa Rica, El Salvador, Guatemala , Honduras, Nicaragua, Dominician republic and Panama ii) Approved : Not submitted. iii) Approved as IND : Naproxen was approved by the FDA on December 1991. iv) withdrawn, if any, with reasons :	This FDC was discussed by previous "10 expert Committee" on 04.06.14 which stated that: "There is no scientific justification, the only published literature of this combination has used Paracetamol 4g/day which is much higher than the proposed dose in the FDC. Hence, the committee did not recommend." The Subcommittee concurred with the comments of "10 expert committee" and noted that: 1. There is no published data on combination of Naproxen + Paracetamol at the dose used in this FDC being better when compared to individual drug. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredient. There is no convincing scientific/ clinical evidence/ justification for the FDC.
12	S.O. 716(E)	Naproxen+ Paracetamol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: The Subcommittee is of the opinion that: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 717(E)	Nimesulide + serratiopeptidase	Akums Drugs	Combikit of:- A- Nimesulide BP 100mg+ serratiopeptidase IP 10mg (eq. To 20,000 unit of serratiopeptidase as entric coated granules) film coated tablet B- Nimesulide BP 100mg+ serratiopeptidase IP 15mg (eq. To 30,000 unit of serratiopeptidase as entric coated granules) uncoated tablet	For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.	i. Same as per Annexure A ii. Not approved	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) andits use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 717(E)	Nimesulide + serratiopeptidase	Ruby Organics	Nimesulide BP 100mg+ Serratiopeptidase IP 15mg (30,000 Serratiopeptase units) film coated tablet	Is used as anti inflammatory and analgesic.	i. Not Submitted ii. Not submitted	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) and its use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 717(E)	Nimesulide + serratiopeptidase	Mascot Healthcare	Nimesulide BP 100mg+Serratiopeptidase IP 10mg (30,000 Serratiopeptase units) film coated tablet	Anti inflammatory,Analgesic	i. Indication mentioned in package insert is for individual ingredients and not for FDC. Ii. Not approved	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) andits use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 717(E)	Nimesulide + serratiopeptidase	Obsurge Biotech Ltd.	Nimesulide 100mg+ serratiopeptidase 15mg (as enteric coated) (eq. to enzyme activity 30000 units)	Anti-inflammatory,Analgesic	i. Indications mentioned in package insert are: Trauma Surgery, Surgery, Plastic surgery, Respiratory medicine, infections, dermatology, dentistry, obstetrics and gynaecology. Ii. Not mentioned	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) andits use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 717(E)	Nimesulide + serratiopeptidase	Skymap Pharmaceutical	Nimesulide BP 100mg+Serratiopeptidase IP 10mg (Eq. to 20,000 enzymatic units) film coated tablet	Analgesic	i. Not Submitted ii. Not submitted	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) andits use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 717(E)	Nimesulide + serratiopeptidase	Lark Laboratories	Nimesulide BP 100mg+Serratiopeptidase 10mg (eq. to 20000 units of enzymatic activity) capsule	To treat Pain and fever, inflammation	i. Not Submitted ii. Not submitted	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) andits use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 717(E)	Nimesulide + serratiopeptidase	Horizon Bioceuticals	Nimesulide BP 100mg+Serratiopeptidase IP 10mg (Enteric coated eq. to 20000 units) uncoated tablet	Anti inflammatory and analgesic	i. same as per Annexure A ii. Not approved	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) andits use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 717(E)	Nimesulide + serratiopeptidase	Meridian Medicare	Nimesulide BP 100mg+Serratiopeptidase 10mg/15mg	Acute inflammatory pain, painful osteoarthritis, primary dysmenorrhoea, post-partum haematomas, breastengorgements, post operative trauma, painful inflamed dermatoses, dental infections & inflammation sports injury.	i. Not Submitted ii. Not submitted	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) andits use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 717(E)	Nimesulide + serratiopeptidase	TTK Healthcare	Nimesulide BP 100mg+Serratiopeptidase eq. to 30000 units of Serratiopeptidase (as enteric coated granules) 15mg	Antiinflammatory- Analgesic	i. Indications in packag insert do not match as per Annexure A. Indications mentioned in Annexure A are: Nimesulide tablet is used in conditions of pain with severe inflammation, such as trauma, fractures, post-operative condition, gynaecological procedures, dental infections and ENT infections etc. ii. Not submitted	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) andits use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 717(E)	Nimesulide + serratiopeptidase	Navil Laboratories	Nimesulide BP 100mg+ Serratiopeptidase 15mg Tablets	Analgesic and antipyretic	i. Not Submitted ii. India	1. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 2. Nimesulide has safety concern (hepatotoxicity) andits use in children below 12 years is already banned in India. It is not permitted for more than 15 days in adults in Europe. There is no convincing scientific/ clinical evidence/ justification for the FDC.
13	S.O. 717(E)	Nimesulide + serratiopeptidase	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	I. Indication as per package insert ii. If marketing any where	
	S. O. 718(E)	Paracetamol + Diclofenac + Famotidine	Horizon Bioceuticals	Diclofenac potassium BP 50mg+ Paracetamol IP 325mg+ Famotidine IP 10mg uncoated tablet	Anti inflammatory, analgesic antipyretic and anti ulcer	i) same as Annexure A ii) Not submitted	1. Pharmacokinetically irrelevant as each ingredient has different dosing schedule/dosing requirement (Diclofenac 2-3 times a day, Paracetamol 4-6 hourly for fever and pain SOS and Famotidine once or twice daily). 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects The Subcommittee noted that this FDC is promoted by the appellant with the therapeutic claim put under indication "anti-ulcer" which is not acceptable because of presence of diclofenac which is ulcerogenic and addition of famotidine will not prevent small intestinal ulcers caused by Diclofenac. There is no convincing scientific/ clinical evidence/ justification for the FDC.
14	S. O. 718(E)	Paracetamol + Diclofenac + Famotidine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O.719(E)	Nimesulide + Pitofenone + Fenpiverinium + benzyl alcohol	-	-	-	-	1. There is no published clinical evidence to suggest any benefit of this FDC combining Nimesulide with antispasmodic (Pitofenone and Fenpiverinium). 2. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe .Nimesulide in combination in injectable form has strong potential of misuse. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
15	S.O.719(E)	Nimesulide+ Pitofenone+ Fenpiverinium+ benzyl alcohol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 720(E)	Omeprazole + Paracetamol + Diclofenac	Akums Drugs	Omeprazole Magnesium USP eq. To Omeprazole 10mg+ Paracetamol IP 500mg+ Diclofenac Potassium BP 50mg film coated tablet	Indicated for pain and inflammation associated with musculoskeletal and joint disorders including low back pain. Spondilitis,Frozen Shoulder, joint stiffness, sprains & strains, fractures,dislocations, dysmenorhea, dental pain, muscle pain, duodenal ulcer, gastric ulcer, reflux osteoarthritis & Zollinger-ellison syndrome. If duodenal ulcer are associated with helicobacter pylori.	i. Same as per Annexure A ii. Not submitted	1. Pharmacokinetic mismatch:Diclofenac is given three times a day; Omeprazole is administered once a day and Paracetamol four times a day. Additionally, Omeprazole is given on an empty stomach whereas diclofenac and Paracetamol should be given after food. 2.Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 3. No convincing benefit of this triple drug FDC. There is no convincing scientific/ clinical evidence/ justification for the FDC.
16	S.O. 720(E)	Omeprazole + Paracetamol + Diclofenac	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **The Subcommittee is of the opinion that:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 721(E)	Nimesulide + Paracetamol injection	-	-	-	-	1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. Nimesulide in combination in injectable form has strong potential of misuse in children. 2. Nimesulide and Paracetamol both have hepatotoxic potential. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. 4. Pharmacokinetic mismatch: Nimesulide is given once or twice a day whereas Paracetamol is given four times a day. There is no convincing scientific/ clinical evidence/ justification for the FDC.
17	S.O. 721(E)	Nimesulide + Paracetamol injection	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 722(E)	Tamsulosin + Diclofenac	-	-	-	-	The Subcommittee perused the FDC and comments are as follows: 1. Both the ingredients have different indications and there is no condition in which they are required in combination. 2. Also, inadvertent and prolonged use of diclofenac in this FDC may cause serious adverse effects. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
16	S.O. 722(E)	Tamsulosin + Diclofenac	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings and animals.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 723(E)	Paracetamol+ Phenylephirine+ Chlorpheniramine+ Dextromethorphan+ Caffeine	-	-	-	-	1. There is no rationale in combining five ingredients in single FDC as this will only lead to unnecessary exposure to too many medicines. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard the guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
19	S.O. 723(E)	Paracetamol+ Phenylephirine+ Chlorpheniramine+ Dextromethorphan+ Caffeine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 724(E)	Diclofenac+ Zinc Carnosine	Akums Drugs	Diclofenac Potassium BP 50mg+Zinc Carnosine 37.5mg film coated tablet	For the pain management with protection of Diclofenac NSAID) induced gastric complications, gastric mucosal damage & ulcers.	i. Same as per annexu a ii. Not submitted	1. There is no experimental or clinical evidence to suggest that zinc carnosine, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Diclofenac. On the other hand, the prescriber may be encouraged to use diclofenac in larger dose or longer duration. There is no convincing scientific/ clinical evidence/ justification for the FDC.
20	S.O. 724(E)	Diclofenac+ Zinc Carnosine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: The Subcommittee is of the opinion that: There is no therapeutic justification for the ingredients of this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	Laborate	Paracetamol IP 325mg+ Chlorpheniramine Maleate IP 4mg+ Diclofenac Sodium IP (as enteric coated granules) 50mg+ Magnesium Trisilicate IP 100mg uncoated tablet	Antipyretic , analgesics and anti histaminic.	i. Same as per annex A ii. submitted i) Marketed : Nigeria ii) Approved :Nigeria iii) Approved as IND : iv) withdrawn, if any, with reasons : Appellant informed at the time of hearing that they are marketing the product in Tajikistan, Turkmenistan and Republic of Congo but no longer in Nigeria.	1. Each ingredient has different indication and there is no pharmacodynamic rationale for combining these ingredients. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	Akums Drugs	Diclofenac Sodium IP 50mg (as enteric coated granules)+ Paracetamol IP 500mg+ Chlorpheniramine maleate IP 4mg+ Magnesium trisillicate IP 100mg uncoated tablet	Symptomatic relief from minor aches and pain like body ache, headache,toothache, muscular pain, backache, fever etc.	i. Same as per annex A ii. submitted i) Marketed : Nigeria ii) Approved :Nigeria iii) Approved as IND : iv) withdrawn, if any, with reasons :	1. Each ingredient has different indication and there is no pharmacodynamic rationale for combining these ingredients. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	Horizon Biocceuticals	Diclofenac Potassium BP 50mg+ paracetamol IP 325mg+ chlorpheniramine maleate IP 4mg+ magnesium trisillicate IP 100mg uncoated tablet	Antiinflammatory, analgesic and antipyretic and cough suppressant	i. Same as per annex A ii. Not submitted	1. Each ingredient has different indication and there is no pharmacodynamic rationale for combining these ingredients. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	Horizon Biocceuticals	Diclofenac Sodium IP 50mg + Paracetamol IP 325mg+ Chlorpheniramine maleate IP 4mg+ Magnesium trisillicate IP 100mg uncoated tablet	Antiinflammatory, analgesic and antipyretic and cough suppressant	i. Same as per annex A ii. Not submitted	1. Each ingredient has different indication and there is no pharmacodynamic rationale for combining these ingredients. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	Combitic Global	Diclofenac Sodium IP 50mg+ paracetamol IP 500mg+ chlorpheniramine maleate IP 4mg+ magnesium trisillicate IP 100mg uncoated tablet	Anti inflammatory, Anti pyretic and Anti allergic	i. Not Submitted ii. Not submitted	1. Each ingredient has different indication and there is no pharmacodynamic rationale for combining these ingredients. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	Combitic Global	Diclofenac Sodium IP 50mg+ paracetamol IP 300mg+ chlorpheniramine maleate IP 4mg+ magnesium trisillicate IP 100mg uncoated tablet	Anti inflammatory, Anti pyretic and Anti allergic	i. Not Submitted ii. Not submitted	1. Each ingredient has different indication and there is no pharmacodynamic rationale for combining these ingredients. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	Combitic Global	Diclofenac Sodium IP 50mg+ paracetamol IP 300mg+ chlorpheniramine maleate IP 4mg+ magnesium trisillicate IP 100mg uncoated tablet	Anti inflammatory, Anti pyretic and Anti allergic	i. Not Submitted ii. Not submitted	1. Each ingredient has different indication and there is no pharmacodynamic rationale for combining these ingredients. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	Combitic Global	Diclofenac Sodium IP 50mg+ paracetamol IP 300mg+ chlorpheniramine maleate IP 4mg+ magnesium trisillicate IP 100mg uncoated tablet	Anti inflammatory, Anti pyretic and Anti allergic	i. Not Submitted ii. Not submitted	1. Each ingredient has different indication and there is no pharmacodynamic rationale for combining these ingredients. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	Combitic Global	Diclofenac Sodium IP 50mg+ paracetamol IP 300mg+ chlorpheniramine maleate IP 4mg+ magnesium trisillicate IP 100mg uncoated tablet	Anti inflammatory, Anti pyretic and Anti allergic	i. Not Submitted ii. Not submitted	1. Each ingredient has different indication and there is no pharmacodynamic rationale for combining these ingredients. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 3. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
24	S.O. 725(E)	Diclofenac+ paracetamol+ chlorpheniramine maleate+ magnesium trisillicate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for ingredients of this FDC. The FDC may involve risk to human beings and animals.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 726(E)	Paracetamol+ Pseudoephedrine+ Cetirizine	-	-	-	-	1. The FDC is pharmacokinetically incompatibile: Paracetamol is given 4 times a day whereas Cetirizine is given once a day. 2. Patients may need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
22	S.O. 726(E)	**Paracetamol+ Pseudoephedrine+ Cetirizine**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 727(E)	Phenylbutazone+ Sodium Salicylate	-	-	-	-	1. The FDC has high risk of toxicity 2.Fixed dose combination of Phenylbutazone with any other drug is already banned in India. (GSR NO. 633(E) Dated13.09.1995)
A2	S.O. 727(E)	Phenylbutazone+ Sodium Salicylate	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 728(E)	Lornoxicam+ Paracetamol+ Trypsin	-	-	-	-	This FDC was discussed by previous Committee on 04.06.14 and comments were as follows: "There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend". The Subcommittee concurred with above comments and further observes that 1. There is Pharmacokinetic mismatch Lornoxicam is given twice daily, Paracetamol four times daily. 2. There is no published clinical evidence to suggest benefit of this FDC. There is no convincing scientific/ clinical evidence/ justification for the FDC.
24	S.O. 728(E)	Lornoxicam+ Paracetamol+ Trypsin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 729(E)	Paracetamol + Mefenamic Acid + Ranitidine + Dicyclomine	Akums Drugs	Paracetamol IP 300mg+ Mefenamic Acid IP 100mg+ Ranitidine HCl IP eq. to Ranitidine 150mg+ Dicyclomine HC IP 10mg film coated tablet	For the treatment of severe spasmodic pain & symptomatic fever	i) same as Annexure A ii) Not submitted	1. There is no scientific evidence as well as justification for use of this combination for the given indications which appear too broad and vague. 2. Paracetamol has no antispasmodic actions and not indicated in spasmodic pain. 3. Pharmacokinetically inappropriate as each ingredient has different dosing schedule/dosing requirement (Mefenamic acid 3-4 times a day, Paracetamol 4-6 hourly for fever and pain SOS, Dicyclomine 4 times a day and ranitidine once or twice daily). 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 729(E)	Paracetamol + Mefenamic Acid + Ranitidine + Dicyclomine	Horizon Bioceuticals	Paracetamol IP 300mg+ Mefenamic Acid IP 100mg+ Ranitidine HCl IP eq. to Ranitidine 150mg+ Dicyclomine HC IP 10mg film coated tablet	Analgesic, Antispamsodic and anti ulcer. (assubmitted)	i) same as Annexure A ii) Not submitted	1. There is no scientific evidence as well as justification for use of this combination for the given indications which appear too broad and vague. 2. Paracetamol has no antispasmodic actions and not indicated in spasmodic pain. 3. Pharmacokinetically inappropriate as each ingredient has different dosing schedule/dosing requirement (Mefenamic acid 3-4 times a day, Paracetamol 4-6 hourly for fever and pain SOS, Dicyclomine 4 times a day and ranitidine once or twice daily). 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects There is no convincing scientific/ clinical evidence/ justification for the FDC.
25	S.O. 729(E)	Paracetamol + Mefenamic Acid + Ranitidine + Dicyclomine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 730(E)	Nimesulide + Dicyclomine	Navil	Nimesulide BP 100mg+ Dicyclomine HCl IP 20mg tablet	For Intestinal Colic, Renal Colic, Biliary Colic, Dysmenorrhea and Irritable bowel syndrome	i) same as Annexure A ii) Not submitted	1. Given the broad indications mentioned by the appellant for the FDC will lead to misuse and toxicity. 2. Nimesulide in combination has potential of misuse and safety concern. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 3. Nimesulide is not indicated in Irritable Bowel Syndrome. 4. There is no clinical evidence for use of this combination for the indications mentioned by the appellant. 5. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 730(E)	Nimesulide + Dicyclomine	J. B. Chemicals	Nimesulide BP 100mg+ Dicyclomine HCl IP 10mg uncoated tablet	For symptomatic treatment of primary dysmenorrhea	i) same as Annexure A ii) Not approved	1. Nimesulide in combination has potential of misuse and safety concern. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 2. Nimesulide is not indicated in Irritable Bowel Syndrome. 3. There is no clinical evidence for use of this combination for the indications mentioned by the appellant. 4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 730(E)	Nimesulide + Dicyclomine	Horizon Bioceuticals	Nimesulide BP 100mg+ Dicyclomine HCl IP 20mg uncoated tablet	Anti Spasmodic, gastrointestinal distress, analgesic	i) Spasmodic dysmenorrhea, gastrointestinal distress II) Not submitted	I. Given the broad indications mentioned by the appellant for the FDC will lead to misuse and toxicity. 2. Nimesulide in combination has potential of misuse and safety concern. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 3. Nimesulide is not indicated in Irritable Bowel Syndrome. 4. There is no clinical evidence for use of this combination for the indications mentioned by the appellant. 5. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 730(E)	Nimesulide + Dicyclomine	DM Pharma	Nimesulide BP 100mg+ Dicyclomine HCl IP 20mg uncoated tablet	Abdominal spasms, Irritable Bowel Syndrome	i) same as Annexure A ii) Not submitted	1. Given the broad indications mentioned by the appellant for the FDC will lead to misuse and toxicity. 2. Nimesulide in combination has potential of misuse and safety concern. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 3. Nimesulide is not indicated in Irritable Bowel Syndrome. 4. There is no clinical evidence for use of this combination for the indications mentioned by the appellant. 5. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 730(E)	Nimesulide + Dicyclomine	Meridian Medicare	Nimesulide BP 100mg+ Dicyclomine HCl IP 20mg uncoated tablet	Spasmodic dysmenorrhea, GI Distress	i) same as Annexure A ii) Not submitted	1. Given the broad indications mentioned by the appellant for the FDC will lead to misuse and toxicity. 2. Nimesulide in combination has potential of misuse and safety concern. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. 3. Nimesulide is not indicated in Irritable Bowel Syndrome. 4. There is no clinical evidence for use of this combination for the indications mentioned by the appellant. 5. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
26	S.O. 730(E)	Nimesulide + Dicyclomine	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 731(E)	Heparin+ Diclofenac	Acon Formulations	Heparin 200IU+Diclofenac sodium 10mg per gm gel	for local symptomatic relief of pain and inflammation in trauma of muscles and joints.	i)Used for the treatment of anti inflammatory, hemorheologic sprain ii) Not available	1. There is no rationale for Heparin in this FDC for the given indication. 2. The appellant submitted information pertaining to Heparin + Diclofenac Plaster. The animal study and clinical study on gel did not have single drug as control group. There is no scientific/ clinical evidence/ justification for the FDC.
27	S.O. 731(E)	Heparin+ Diclofenac	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for ingredients of this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 732(E)	Glucosamine+ Methyl Sulfonyl Methane+ Vitamin D3+ Manganese+ Boron+ Copper+ Zinc	Combitic Global	Glucosamine Potasisum sulpahte USP 750mg+ Methyl Sulfonyl Methane (MSM) 200mg+ Vitamin D3 IP 200IU+ Maganese sulpahte monohydrate USP eq. to elemental manganese 3mg+ Sodium borate decahydrate BP eq. to elemental Boron 0.5mg+ Copper sulphate monohydrate USP eq. to elemental copper 0.5mg+ Zinc sulphate monohydrate USP eq. to elemental Zinc 3mg film coated tablet	Dietary Supplement	i) Not submitted ii) Not provided	1. Pharmacodynamically irrelevant. MSM has questionable therapeutic benefit. Addition of Vitamin D and micronutrients to such combination, without any clear rationale, is tantamount to unnecessary polypharmacy. 2. Therapeutic efficacy of FDC not established. Company has stated indication as dietary supplements. There is no convincing scientific/ clinical evidence/ justification for the FDC.
28	S.O. 732(E)	Glucosamine+ Methyl Sulfonyl Methane+ Vitamin D3+ Manganese+ Boron+ Copper+ Zinc	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for ingredients in this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 733(E)	Paracetamol+ Tapentadol	Comed Chemicals	Tapentadol 50mg+ Paracetamol 325mg tablet	Osteoarthritis, Fracture, Lumbago, Spondylitis, Neuritis, Post operative pain, PIVD.	i) Same ii) Not approved	This FDC was discussed by previous Committee on 04.06.14 as under- "The firm did not turn up for the presentation. The committee noted that the proposal had already been discussed in NDAC on 17.03.2012 and the committee agreed with the recommendations of the NDAC (The committee considered the proposal and also the written opinions of other members and opined that the proposed FDC is not required in majority of the patients. Further there is potential for misuse of this combination. Hence the committee did not recommend for approval of the FDC)." The Subcommittee concurs with the above and further it noted that: 1. There are no controlled studies to indicate that the combination may be superior to either drug alone. 2. Tapentadol, being opioid-related, has certain risks, if used indiscriminately. These include respiratory depression, central nervous system (CNS) depressing effects and elevation of intracranial pressure. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects.. There is no convincing scientific/ clinical evidence/ justification for the FDC.
29	S.O. 733(E)	Paracetamol+ Tapentadol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **The Subcommittee is of the opinion that:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 734(E)	Tranexamic Acid + Proanthocyanidin	Windlas Biotech	Tranexamic Acid 250mg+Proanthocyanidin 75mg film coated bilayered tablet	For the treatment of hyperpigmentation in skin of colour (Melasma)	i. Indication Same as Annexure-A ii. Not approved	1. Safety and efficacy of Proanthocyanidin and Tranexamic acid in FDC for the duration as proposed by the firm is not established. 2. This FDC has not been evaluated in any clinical trial for the indication stated. 3. This combination is not as per standard therapeutic guidelines for the management of melasma. There is no clinical evidence for the FDC.
	S.O. 734(E)	Tranexamic Acid + Proanthocyanidin	Windlas Biotech	Tranexamic Acid 250mg+Proanthocyanidin 100mg film coated bilayered tablet	For the treatment of hyperpigmentation in skin of colour (Melasma)	i. Indication Same as Annexure-A ii. Not approved	1. Safety and efficacy of Proanthocyanidin and Tranexamic acid in FDC for the duration as proposed by the firm is not established. 2. This FDC has not been evaluated in any clinical trial for the indication stated. 3. This combination is not as per standard therapeutic guidelines for the management of melasma. There is no clinical evidence for the FDC.
	S.O. 734(E)	Tranexamic Acid + Proanthocyanidin	La Pristine Bioceuticals Pvt Ltd	Tranexamic Acid 250mg+Proanthocyanidin 75mg film coated tablet	Melasma, Hyperpigmentation, Post inflammatory pigmentation, UV induced hyperpigmentation	i. Indication Same as Annexure-A ii. Not approved	1. Safety and efficacy of Proanthocyanidin and Tranexamic acid in FDC for the duration as proposed by the firm is not established. 2. This FDC has not been evaluated in any clinical trial for the indication stated. 3. This combination is not as per standard therapeutic guidelines for the management of melasma. There is no clinical evidence for the FDC.
30	**S.O. 734(E)**	**Tranexamic Acid + Proanthocyanidin**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 735 (E)	Benzoxonium Chloride+ Lidocaine	Ajanta	Benzoxonium Chloride 1mg+ Lidocaine HCl 1mg chewable tablet	Pain caused by mouth ulcers, infections of throat, numbness, pain caused by denture irritation and other conditions.	i) same ii) Not submitted At the time of hearing, the company informed that the product is marketed in 15 European countries.	The Subcommittee noted that Kokate committee has considered this FDC as 'rational' in chewable tablets if used for local purpose and not for systemic use. This was informed to MoH & FW, Government of India vide letter dated 27.05.2016. The MoH&FW, Government of India accepted the said proposal. As this FDC is part of the 344 + 05 FDCs, the Subcommittee has reviewed it as per supreme court order. Subcommittee's comments are as below: 1. Benzoxonium carries risk of contact allergy, causes browning discolouration of tongue and/or teeth with prolonged use. In view of above, Subcommittee is of the opinion that this FDC can be approved with restrictions as follows: "To be used for local purpose and not for systemic use for duration not longer than two weeks for gingivitis, mild infections and ulcers of oral mucosa. All other standard contraindications and precautions for individual ingredients shall be mentioned in the package insert."
31	S.O. 735 (E)	Benzoxonium Chloride+ Lidocaine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **Use of this FDC shall be restricted to "To be used for local purpose and not for systemic use for duration not longer than two weeks for gingivitis, mild infections and ulcers of oral mucosa. All other standard contraindications and precautions for individual ingredients shall be mentioned in the package insert".** **Hence in the larger public interest, it is necessary to restrict the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940 as above.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 736(E)	Lornoxicam +Paracetamol +Tramadol	SunDyota Numandis	Lornoxicam 8mg+ Paracetamol IP 325mg + Tramadol HCLIP 37.5mg film coated bilayered tablet	Treatment of moderate to severe pain in adults.	i) Same ii) Not approved	The Subcommittee noted that this FDC was discussed by previous Committee on 04.06.14- "There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend." The Subcommittee concurred with the above. Further, Subcommittee noted that: 1. There is Pharmacokinetic mismatch Lornoxicam is given twice daily, Paracetamol four times daily and Tramadol three to four times daily. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. Presence of Tramadol confers abuse potential. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 736(E)	Lornoxicam+ Paracetamol+ Tramadol	Windlas Biotech	Lornoxicam 8mg+ Paracetamol IP 325mg + Tramadol HCLIP 37.5mg film coated bilayered tablet	Treatment of moderate to severe pain in adults.	i) Same ii) Not approved	The Subcommittee noted that this FDC was discussed by previous Committee on 04.06.14- "There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend." The Subcommittee concurs with the above. Further, Subcommittee noted that: 1. There is Pharmacokinetic mismatch Lornoxicam is given twice daily, Paracetamol four times daily and Tramadol three to four times daily. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. Presence of Tramadol confers abuse potential. There is no convincing scientific/ clinical evidence/ justification for the FDC.
32	S.O. 736(E)	Lornoxicam+ Paracetamol+ Tramadol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 737(E)	Lornoxicam +Paracetamol +Serratiopeptidase	SunDyota Numandis	Lornoxicam 8mg+Paracetamol 325mg+Serratiopeptidase 15mg tablets	Treatment of oedematous painful inflammatory condition in adults.	i)For the oedematous painful inflammatory condition ii) Not approved	The Subcommittee noted that this FDC was discussed by previous Committee on 04.06.14- "There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend." The Subcommittee concurred with the above. Further, Subcommittee noted that: 1. There is a Pharmacokinetic mismatch: Lornoxicam is given twice daily, Paracetamol four times daily. 2. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 3. There is no therapeutic justification for use of these three drugs as FDC. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 737(E)	Lornoxicam + Paracetamol + Serratiopeptidase	Windlas Biotech	Lornoxicam 8mg+ Paracetamol 325mg+ Serratiopeptidase 15mg tablets	Treatment of oedematous painful inflammatory condition in adults.	i) For the oedematous painful inflammatory condition ii) NA	The Subcommittee noted that this FDC was discussed by previous Committee on 04.06.14- "There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend." The Subcommittee concurs with the above. Further, Subcommittee noted that: 1. There is Pharmacokinetic mismatch: Lornoxicam is given twice daily, Paracetamol four times daily. 2. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 3. There is no therapeutic justification for use of these three drugs as FDC. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
33	S.O. 737(E)	Lornoxicam + Paracetamol + Serratiopeptidase	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **The Subcommittee is of the opinion that:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 738(E)	Diclofenac + Paracetamol + Magnesium trisilicate	Horizon Bioceuticals	Diclofenac Potassium BP 50mg+ Paracetamol IP 325mg+ Magnesium trisilicate IP 100mg uncoated tablet	Anti inflammatory, analgesic and antipyretic	i) Anti inflammatory, analgesic and antipyretic and anti ulcer ii) Not submitted	1. Patients may need only one ingredient (Diclofenac or Paracetamol) and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 2. There is no experimental or clinical evidence to suggest that magnesium trisilicate, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Diclofenac. Such misconception of gastrointestinal safety can lead to misuse. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 738(E)	Diclofenac + Paracetamol + Magnesium trisilicate	Combitic Global	Diclofenac Potassium IP 50mg+ Paracetamol IP 325mg+ Magnesium trisilicate IP 150mg uncoated tablet	Analgesic and Anti Pyretic	i) Not submitted ii) Not provided	1. Patients may need only one ingredient (Diclofenac or Paracetamol) and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 2. There is no experimental or clinical evidence to suggest that magnesium trisilicate, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Diclofenac. Such misconception of gastrointestinal safety can lead to misuse. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 738(E)	Diclofenac + Paracetamol + Magnesium trisilicate	Combitic Global	Diclofenac Potassium BP 50mg+ Paracetamol BP 325mg+ Magnesium trisilicate BP 100mg uncoated tablet	Analgesic and Anti Pyretic	i) Not submitted ii) Not provided	1. Patients may need only one ingredient (Diclofenac or Paracetamol) and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 2. There is no experimental or clinical evidence to suggest that magnesium trisilicate, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Diclofenac. Such misconception of gastrointestinal safety can lead to misuse. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 738(E)	Diclofenac + Paracetamol + Magnesium trisilicate	Combitic Global	Diclofenac Potassium IP 50mg+ Paracetamol IP 325mg+ Magnesium trisilicate IP 100mg uncoated tablet	Analgesic and Anti Pyretic	i) Not submitted ii) Not provided	1. Patients may need only one ingredient (Diclofenac or Paracetamol) and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 2. There is no experimental or clinical evidence to suggest that magnesium trisilicate, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Diclofenac. Such misconception of gastrointestinal safety can lead to misuse. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 738(E)	Diclofenac + Paracetamol + Magnesium trisilicate	Combitic Global	Diclofenac Potassium IP 50mg+ Paracetamol IP 325mg+ Magnesium trisilicate IP 100mg uncoated tablet	For treatment of Pain and fever	i) Not submitted ii) Not provided	1. Patients may need only one ingredient (Diclofenac or Paracetamol) and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 2. There is no experimental or clinical evidence to suggest that magnesium trisilicate, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Diclofenac. Such misconception of gastrointestinal safety can lead to misuse. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 738(E)	Diclofenac + Paracetamol + Magnesium trisilicate	Combitic Global	Diclofenac Potassium IP 50mg+ Paracetamol IP 300mg+ Magnesium trisilicate IP 100mg uncoated tablet	Analgesic and Anti pyretic	i) Not submitted ii) Not provided	1. Patients may need only one ingredient (Diclofenac or Paracetamol) and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 2. There is no experimental or clinical evidence to suggest that magnesium trisilicate, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Diclofenac. Such misconception of gastrointestinal safety can lead to misuse. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 738(E)	Diclofenac + Paracetamol + Magnesium trisilicate	Combitic Global	Diclofenac Potassium IP 50mg+ Paracetamol IP 500mg+ Magnesium trisilicate IP 100mg uncoated tablet	Analgesic and Anti pyretic	i) Not submitted ii) Not provided	1. Patients may need only one ingredient (Diclofenac or Paracetamol) and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 2. There is no experimental or clinical evidence to suggest that magnesium trisilicate, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Diclofenac. Such misconception of gastrointestinal safety can lead to misuse. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 738(E)	Diclofenac + Paracetamol + Magnesium trisilicate	Combitic Global	Diclofenac Potassium IP 50mg+ Paracetamol IP 325mg+ Magnesium trisilicate IP 100mg uncoated tablet	Analgesic and Anti pyretic	i) Not submitted ii) Not provided	1. Patients may need only one ingredient (Diclofenac or Paracetamol) and use of this FDC may lead to unnecessary exposure to other ingredients with risk of ADRs. 2. There is no experimental or clinical evidence to suggest that magnesium trisilicate, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Diclofenac. Such misconception of gastrointestinal safety can lead to misuse. There is no convincing scientific/ clinical evidence/ justification for the FDC.
34	S.O. 738(E)	Diclofenac + Paracetamol + Magnesium trisilicate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **The Subcommittee is of the opinion that:** **There is no therapeutic justification for ingredients of this FDC. The FDC may involve risk to human beings and animals.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 739(E)	Paracetamol + Domperidone + Caffeine	Akums Drugs	Paracetamol 650mg+ Domperidone 10mg+ Caffeine 50mg uncoated tablet	For the management of migraine pain and related symptoms such as nausea and vomiting	i)same ii) Not submitted	1. Many migraine episodes are not associated with nausea-vomiting so that use of this combination would mean unnecessary exposure to Domperidone. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no convincing justification for caffeine in migraine headache. Even as an adjuvant to Paracetamol, the dose of Caffeine in this FDC is inadequate. 4. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification submitted for the FDC.
35	S.O. 739(E)	Paracetamol + Domperidone + Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for ingredients of this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A			i) Indication as per package insert ii) If marketing any where	Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)		
	S.O. 740(E)	Ammonium Chloride+ Sodium Citrate+ Chlorpheniramine Maleate+ Menthol	Seagull	Ammonium Chloride IP 4mg+ Sodium Citrate IP 55mg+ Chlorpheniramine Maleate IP 4mg+ Menthol IP 1mg per 5ml oral liquid	Not submitted	i) Package insert not submitted. ii) Not submitted	The Subcommittee noted that CDSCO has withdrawn the approval as it was issued inadvertently. Subcommittee also noted that this FDC was again deliberated by Kokate committee in its meeting held on 26th and 27th May 2016 while reviewing the FDCs prohibited by Government of India. The Kokate committee after review has also finally categorised this FDC as 'irrational'. The Subcommittee further noted that: 1. Pharmacodynamically antagonisticand hence inappropriate (Ammonium chloride, Sodium citrate are expectorant whereas Chlorpheniramine is cough suppressant so expulsion of secretion would be hampered). 2. No identifiable patient population/group has been stated by the apellant for which this combination is indicated. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 740(E)	Ammonium Chloride+ Sodium Citrate+ Chlorpheniramine Maleate+ Menthol	Laborate Pharmaceutical	Ammonium Chloride IP 50mg+ Sodium Citrate IP 25mg+ Chlorpheniramine Maleate IP 2mg+ Menthol IP 0.35mg per 5ml syrup	Antitusive and expectorant cough mixture	i) Package insert mentions that the FDC is also used in the treatment of brochospam in addition to perennial and seasonal allergic rhinitis, vasomotor rhinitis, common cold, sinusitis associated with fever and bodyache etc. ii) Not submitted	The Subcommittee noted that CDSCO has withdrawn the approval as it was issued inadvertently. The Subcommittee also noted that this FDC was again deliberated by Kokate committee in its meeting held on 26th and 27th May 2016 while reviewing the FDCs prohibited by Government of India. The Kokate committee after review has also finally categorised this FDC as 'irrational'. The Subcommittee further noted that: 1. Pharmacodynamically antagonisticand hence inappropriate (Ammonium chloride, Sodium citrate are expectorant whereas Chlorpheniramine is cough suppressant so expulsion of secretion would be hampered). 2. No identifiable patient population/group has been stated by the apellant for which this combination is indicated. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 740(E)	Ammonium Chloride+ Sodium Citrate+ Chlorpheniramine Maleate+ Menthol	Biogenetic Drugs	Ammonium Chloride IP 130mg+ Sodium Citrate IP 65mg+ Chlorpheniramine Maleate IP 3mg+ Menthol IP 0.5mg per 5ml syrup	Broad spectrum antibiotic	i) Package insert not submitted. ii) Not submitted	The Subcommittee noted that CDSCO has withdrawn the approval as it was issued inadvertently. The Subcommittee also noted that this FDC was again deliberated by Kokate committee in its meeting held on 26th and 27th May 2016 while reviewing the FDCs prohibited by Government of India. The Kokate committee after review has also finally categorised this FDC as 'irrational'. The Subcommittee further noted that: 1. Pharmacodynamically antagonisticand hence inappropriate (Ammonium chloride, Sodium citrate are expectorant whereas Chlorpheniramine is cough suppressant so expulsion of secretion would be hampered). 2. No condition has been specified; instead classified under wrong therapeutic category. 3.No identifiable patient population/group has been stated by the apellantfor which this combination is indicated. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 740(E)	Ammonium Chloride+ Sodium Citrate+ Chlorpheniramine Maleate+ Menthol	Labindoss Ltd.	Ammonium Chloride IP 100mg+ Sodium Citrate IP 30mg+ Chlorpheniramine Maleate IP 2mg+ Menthol IP 0.5mg per 5ml syrup	For use in upper respiratory tract infection including the common cold and bronchitis, nonproductive cough (dry cough)	i) Package insert not submitted. ii) Not submitted	The Subcommittee noted that CDSCO has withdrawn the approval as it was issued inadvertently. The Subcommittee also noted that this FDC was again deliberated by Kokate committee in its meeting held on 26th and 27th May 2016 while reviewing the FDCs prohibited by Government of India. The Kokate committee after review has also finally categorised this FDC as 'irrational'. The Subcommittee further noted that: 1. Pharmacodynamically antagonisticand hence inappropriate (Ammonium chloride, Sodium citrate are expectorant whereas Chlorpheniramine is cough suppressant so expulsion of secretion would be hampered). 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 740(E)	Ammonium Chloride+ Sodium Citrate+ Chlorpheniramine Maleate+ Menthol	Labinduss Ltd.	Ammonium Chloride IP 100mg+ Sodium Citrate IP 50mg+ Chlorpheniramine Maleate IP 2mg+ Menthol IP 1mg per 5ml syrup	For use in upper respiratory tract infection including the common cold and bronchitis .Non productive cough (dry cough)	i) Package insert not submitted. ii) Not submitted	The Subcommittee noted that CDSCO has withdrawn the approval as it was issued inadvertently. The Subcommittee also noted that this FDC was again deliberated by Kokate committee in its meeting held on 26th and 27th May 2016 while reviewing the FDCs prohibited by Government of India. The Kokate committee after review has also finally categorised this FDC as 'irrational'. The Subcommittee further noted that: 1. Pharmacodynamically antagonisticand hence inappropriate (Ammonium chloride, Sodium citrate are expectorant whereas Chlorpheniramine is cough suppressant so expulsion of secretion would be hampered). 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 740(E)	Ammonium Chloride+ Sodium Citrate+ Chlorpheniramine Maleate+ Menthol	Smilax Healthcare	Chlorpheniramine Maleate IP 3mg+ Ammonium Chloride IP 130mg+ Sodium Citrate IP 65mg+ Menthol IP 0.5mg per 5ml syrup	Broad spectrum antibiotic	i) Package insert not submitted. ii) Not approved	The Subcommittee noted that CDSCO has withdrawn the approval as it was issued inadvertently. The Subcommittee also noted that this FDC was again deliberated by Kokate committee in its meeting held on 26th and 27th May 2016 while reviewing the FDCs prohibited by Government of India. The Kokate committee after review has also finally categorised this FDC as 'irrational'. The Subcommittee further noted that: 1. Pharmacodynamically antagonisticand hence inappropriate (Ammonium chloride, Sodium citrate are expectorant whereas Chlorpheniramine is cough suppressant so expulsion of secretion would be hampered). 2.No condition has been specified; instead classified under wrong therapeutic category. 3.No identifiable patient population/group has been stated by the apellant for which this combination is indicated. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 740(E)	Ammonium Chloride+ Sodium Citrate+ Chlorpheniramine Maleate+ Menthol	Varav Biogenesis	Ammonium Chloride IP 75mg+ Sodium Citrate IP 50mg+ Chlorpheniramine Maleate IP 2mg+ Menthol IP 2mg per 5ml syrup	Expectorant	i) In package insert mentioned as productive cough associated with infections,allergy and fucntional disorders in lower respiratory tract. ii) Not submitted	Subcommittee noted that CDSCO has withdrawn the approval as it was issued inadvertently. Subcommittee also noted that this FDC was again deliberated by Kokate committee in its meeting held on 26th and 27th May 2016 while reviewing the FDCs prohibited by Government of India. The Kokate committee after review has also finally categorised this FDC as 'irrational'. Subcommittee further noted that: 1. Pharmacodynamically antagonisticand hence inappropriate (Ammonium chloride, Sodium citrate are expectorant whereas Chlorpheniramine is cough suppressant so expulsion of secretion would be hampered). 2. No identifiable patient population/group has been stated by the apellant for which this combination is indicated. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 740(E)	Ammonium Chloride+ Sodium Citrate+ Chlorpheniramine Maleate+ Menthol	Meridian Medicare	Ammonium Chloride 80mg+ Sodium Citrate 100mg+ Chlorpheniramine Maleate 2.5mg+ Menthol 1.25mg	Expectorant productive cough	I) Not submitted ii) Not submitted	The Subcommittee noted that CDSCO has withdrawn the approval as it was issued inadvertently. The Subcommittee also noted that this FDC was again deliberated by Kokate committee in its meeting held on 26th and 27th May 2016 while reviewing the FDCs prohibited by Government of India. The Kokate committee after review has also finally categorised this FDC as 'irrational'. The Subcommittee further noted that: 1. Pharmacodynamically antagonisticand hence inappropriate (Ammonium chloride, Sodium citrate are expectorant whereas Chlorpheniramine is cough suppressant so expulsion of secretion would be hampered). 2. No identifiable patient population/group has been stated by the apellant for which this combination is indicated. There is no sound scientific/ clinical evidence/ justification for the FDC.
36	S.O. 740(E)	Ammonium Chloride+ Sodium Citrate+ Chlorpheniramine Maleate+ Menthol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 741(E)	Paracetamol + Prochlorperazine Maleate	Akums Drugs	Prochlorperazine Maleate IP 5mg+Paracetamol IP 650mg uncoated tablet	For the treatment of migraine	i) Indication mentioned in package insert is different from above. Indications mentioned in package insert are: For the symptomatic management of psychotic disorders, short term management of non-psychotic anxiety in patients with generalized anxiety disorder, for the control of vertigo, severe nausea and vomiting of various cases & for the temporary relief of fever & aches. ii) Not approved	The Subcommittee noted that the kokate committee has reviewed this FDC and commented as under: "The kokate committee observed that the FDC was categorized as 'a' i.e. irrational, inadvertently in the report due to typographical error, as similar FDCs have been considered as rational at S. No's 270 and 1376 of the committee report. Therefore the committee recommends that FDC of Paracetamol + Prochlorperazine shall be considered as rational". The DTAB Subcommittee reviewed this FDC and noted that: 1. Treatment guidelines mention use of Paracetamol and Prochlorperazine in acute attack of migraine. The Subcommittee opined that the FDC of Paracetamol and Prochlorperazine in usual therapeutic doses is rational for the treatment of acute migraine attack only. It recommends that the use of this FDC (Paracetamol 500/650 mg + Prochlorperazine 5 mg) shall be restricted "for treatment of acute migraine attack associated with nausea and/ or vomiting in adults only".

me

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 741(E)	Paracetamol + Prochlorperazine Maleate	Horizon Bioceuticals	Paracetamol +Prochlorperazine Maleate	antipsychotic , antiemetic analgesic and antipyretic	i) same as Annexure A ii) Not submitted	The Subcommittee noted that the kokate committee has reviewed this FDC and commented as under: "The kokate committee observed that the FDC was categorized as 'a' i.e. irrational, inadvertently in the report due to typographical error, as similar FDCs have been considered as rational at S. No's 270 and 1376 of the committee report. Therefore the committee recommends that FDC of Paracetamol + Prochlorperazine shall be considered as rational". The DTAB Subcommittee reviewed this FDC and noted that: 1. Treatment guidelines mention use of Paracetamol and Prochlorperazine in acute attack of migraine. The Subcommittee opined that the FDC of Paracetamol and Prochlorperazine in usual therapeutic doses is rational for the treatment of acute migraine attack only. It recommends that the use of this FDC (Paracetamol 500/650 mg + Prochlorperazine 5 mg) shall be restricted "for treatment of acute migraine attack associated with nausea and/ or vomiting in adults only".
37	S.O. 741(E)	Paracetamol + Prochlorperazine Maleate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **The use of this FDC is rational but that the use of this FDC (Paracetamol 500/650 mg + Prochlorperazine maleate 5 mg) shall be restricted "for treatment of acute migraine attack associated with nausea and/ or vomiting in adults only".** **Hence in the larger public interest, it is necessary to restrict the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 742(E)	Combikit of 3 tablets of Serratiopeptidase (enteric coated 20000 units) + Diclofenac Potassium & 2 tablets of Doxycycline	Mascot Healthcare	Each kit contains: (A. 2 tablets each uncoated tablet contains Doxycycline HCl IP eq. to Doxycycline 100mg and (B. 3 tablets each enteric coated tablet contains: Diclofenac Potassium BP 50mg+ Serratiopeptidase IP 10mg(20000 units of serratiopeptidase)	Diarrhoea Respiratory tract infections, Prophylaxis of malaria. B) Join disorders e.g. inflammatory disease in joints, crystal deposition in the joints, antiswelling.	i) package inser does not have indication ii)Not approved	This FDC was deliberated by the "10 expert committee" which opined that: "Co-pack containing an antibiotic and anti-inflammatory agent is not justified. Further the firm was also not able to produce any published literature with respect to the proposed co-pack. Hence, the committee did not recommend." The Subcommittee concurs with above and further observed that: 1. Indications mentioned by the appellant are too broad and not specific. 2. Use of Doxycycline is not indicated in conditions mentioned by the appellant. Combination of Doxycycline (broad spectrum antibiotic) & Diclofenac (NSAID) is irrational and will lead to misuse. 3.Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 742(E)	Combikit of 3 tablets of Serratiopeptidase (enteric coated 20000 units) + Diclofenac Potassium & 2 tablets of Doxycycline	Horizon Bioceuticals	Combikit of 3 tablets of Serratiopeptidase (enteric coated 20000 units) + Diclofenac Potassium & 2 tablets of Doxycycline	Pain and inflammation associated with musculoskeletal and joint disorders At the time of hearing the appellant informed that they want to change the indication to: "Treatment of pain and inflammation after minor surgical procedure".	i) same ii) Not submitted	This FDC was deliberated by the "10 expert committee" which opined that: "Co-pack containing an antibiotic and anti-inflammatory agent is not justified. Further the firm was also not able to produce any published literature with respect to the proposed co-pack. Hence, the committee did not recommend." The Subcommittee concurs with above and further observed that: 1. Indications mentioned by the appellant are too broad and not specific. 2. Use of Doxycycline is not indicated in conditions mentioned by the appellant. Combination of Doxycycline (broad spectrum antibiotic) & Diclofenac (NSAID) is irrational and will lead to misuse. 3.Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
38	S.O. 742(E)	Combikit of 3 tablets of Serratiopeptidase (enteric coated 20000 units) + Diclofenac Potassium & 2 tablets of Doxycycline	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for ingredients of this FDC. The FDC may involve risk to human beings and animals.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

77

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 743(E)	Nimesulide + Paracetamol suspension	-	-	-	-	1. Nimesulide has special safety concern regarding hepatotoxicity and is already banned in India in children below 12 years of age. It is not permitted for more than 15 days in adults in Europe. Nimesulide in combination insuspension form has strong potential of misuse in children. 2. Nimesulide and Paracetamol both have hepatotoxic potential. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
29	S.O. 743(E)	Nimesulide + Paracetamol suspension	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 744(E)	Aceclofenac + Paracetamol + Famotidine	-	-	-	-	1. Pharmacokinetic mismatch as each ingredient has different dosing schedule/dosing requirement (Aceclofenac twice times a day, Paracetamol 3-4 times a day and famotidine once a day). 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
40	S.O. 744(E)	Aceclofenac + Paracetamol + Famotidine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 745(E)	Aceclofenac + Zinc Carnosine	Comed Chemicals	Aceclofenac 100mg+ Zinc Carnosine 37.5mg tablet	OA & RA associated with gastric ulcer.	i) Not submitted ii) Not approved	i. There is no experimental or clinical evidence to suggest that zinc carnosine, administered in oral fixed dose combination, would reduce the incidence or severity of gastrointestinal or other adverse reactions associated with Aceclofenac. Such misconception of gastrointestinal safety can lead to misuse. There is no convincing scientific/ clinical evidence/ justification for the FDC.
41	S.O. 745(E)	Aceclofenac + Zinc Carnosine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients of this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 746(E)	Paracetamol + disodium Hydrogen Citrate + Caffeine	-	-	-	-	1. The indication for this FDC is not clear. 2. There is no rationale for combining Paracetamol with urinary alkalizer (Disodium Hydrogen Citrate). 3. There is no scientific/ clinical evidence/ justification for the FDC.
42	S.O. 746(E)	Paracetamol + disodium Hydrogen Citrate + Caffeine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 747 (E)	Paracetamol + DL Methionine	Geno	Paracetamol IP 125mg+ DL Methionine BP 12.5mg per 5ml suspension	Pain and Fever.	i) Not submitted ii) Not submitted	1. There is no scientific data regarding efficacy of Methionine in preventing Paracetamol toxicity in FDC as claimed by the appellant. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 747 (E)	Paracetamol + DL Methionine	Geno	Paracetamol IP 325mg+ DL Methionine BP 50mg uncoated tablet	Pain and Fever	i) Not submitted ii) Not submitted	1. There is no scientific data regarding efficacy of Methionine in preventing Paracetamol toxicity in FDC as claimed by the appellant. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 747 (E)	Paracetamol + DL Methionine	Strassenburg Pharmaceuticals	Paracetamol IP 500mg/125mg/650mg/1000mg+ DL-Methionine BP 50mg/12.5mg/50mg/100mg uncoated tablet	Mild to moderate pain and pyrexia.	i)Analgesic and antipyretic ii) Not submitted	1. There is no scientific data regarding efficacy of Methionine in preventing Paracetamol toxicity in FDC as claimed by the appellant. There is no convincing scientific/ clinical evidence/ justification for the FDC.
43	S.O. 747 (E)	Paracetamol + DL Methionine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 748(E)	Disodium Hydrogen citrate + Paracetamol	-	-	-	-	1. The indication for this FDC is not clear. 2. There is no rationale for combining Paracetamol with urinary alkalizer (Disodium Hydrogen Citrate). 3. There is no scientific/ clinical evidence/ justification for the FDC.
44	S.O. 748(E)	Disodium Hydrogen citrate + Paracetamol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 749(E)	Paracetamol+ Caffeine+ Codeine Phosphate	-	-	-	-	1. Pharmacodynamically inappropriate FDC: Codeine has abuse potential 2. Patients may need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
45	S.O. 749(E)	Paracetamol+ Caffeine+ Codeine Phosphate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

84

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 750(E)	Aceclofenac (SR) + Paracetamol	-	-	-	-	The Subcommittee noted that this FDC was approved by DCGI as claimed by Sh. Kapil Sibal. The Subcommittee noted that FDC of Aceclofenac 100mg + Paracetamol 325mg tablet is approved by DCGI and not the Aceclofenac in SR form. Comments of Subcommittee are as under: 1. Pharmacokinetic mismatch: Aceclofenac SR is given once daily whereas Paracetamol is given four times a day. 2. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
46	S.O. 750(E)	Aceclofenac (SR) + Paracetamol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 751(E)	Diclofenac + Paracetamol injection	Akums Drugs	Paracetamol IP 75mg+ Diclofenac Sodium IP 25mg per ml injection	Post-traumatic and postoperative pain syndrome accompanied by inflammation and edema. Pain syndrome in inflammatory and degenerative rheumatic disease (rheumatic arthritis, ankylosing spondylitis, ostetoarthritis) when other route of administration are not possible.	i)Indication for individual components has been given ii) Not submitted	1. This is 3ml intramuscular injection and having total dose of Diclofenac 75mg and Paracetamol 225mg. Paracetamol dose is sub therapeutic. 2. There is no published literature to suggest benefit of combined diclofenac and paracetamol injection over diclofenac alone. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effect. 4. Further, Diclofenac poses specific risk to animals (Vultures). There is no convincing scientific/ clinical evidence/ justification for the FDC.
47	S.O. 751(E)	Diclofenac + Paracetamol injection	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	FDC	Cefixime IP as Trihydrate eq. To Anhydrous Cefixime 200mg+ Azithromycin IP as Dihydrate eq. To Anydrous Azithromycin 250mg film coated tablet	Treatment of multi-drug resistant typhoid fever in adults. Treatment of lower respiratory tract infections in adults	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	Magnet	Cefixime IP as Trihydrate eq. To Anhydrous Cefixime 200mg+ Azithromycin IP as Dihydrate eq. To Anydrous Azithromycin 500mg film coated tablet	Is used in the treatment of Typhoid and Lower Respiratory Tract Infections.	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Emcure	Cefixime IP as Trihydrate eq. To Anhydrous Cefixime 200mg+ Azithromycin IP as Dihydrate eq. To Anydrous Azithromycin 250mg film coated tablet	Indicated for treatment of enteric fever caused by susceptible salmonella species or any other infection caused by susceptible microorganisms.	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	Macleods	1. Cefixime IP eq. To Anhydrous Cefixime 200mg/ 200mg+ Azithromycin IP eq. to Anydrous Azithromycin 250mg/ 500mg film coated tablet 2. Cefixime IP eq. To Anhydrous Cefixime 100mg+ Azithromycin IP eq. to Anydrous Azithromycin 125mg uncoated dispersible tablet	It is indicated for the Respiratory Tract infection	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of RTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Aristo	Cefixime IP as Trihydrate eq. To Anhydrous Cefixime 200mg+ Azithromycin IP as Dihydrate eq. To Anydrous Azithromycin 250mg film coated tablet	In the management of Mixed Lower respiratory tract infections, Mixed Gynaecological Infections, Typhoid, Pyrexia of unknown origin	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. Mixed gynaecological infections is a nonspecific indication. Azithromycin and cefixime are not used in the management of common gynaecological conditions such as vaginal delivery, perineal tears, PROM, CS, septic abortion, pelvic surgeries, candidiasis, trichomoniasis and vaginosis. For the treatment of STI – Chlamydia and gonorrhea the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose (National STI guidelines) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. Empiric antibiotics are not indicated for pyrexia of unknown origin. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Glenmark	Azithromycin 250mg/500mg+C efixime 200mg tablet	Empiric Therapy of multidrug Resistant typhoid infection, upon failure of monotherapy	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

90

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Micro	Cefixime IP as Trihydrate eq. To Anhydrous Cefixime 200mg/ 200mg+ Azithromycin IP as Dihydrate eq. To Anydrous Azithromycin 250mg/ 500mg film coated tablet	Respiratory tract infections	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. This combination is not as per standard therapeutic guidelines of RTI. 2. Cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Hetero Labs	Azithromycin 250mg+ Cefixime 200mg tablets	Antibacterial Drug	i. Upper respiratory tract infection (URTI): including otitis media, acute bacterial sinusitis, pharyngitis, tonsillitis. Lower respiratory tract infections including acute exacerbation of chronic bronchitis mild to moderate severe community acquired pneumonia Urinary tract infections: e.g. Cystitis, custourethritis, uncomplicated pyelonephritis chlamydia trachomatis urethritis and cervicitis ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that the indication as per Annexure A is vague (antibacterial drug) while indication in package insert is very broad. Further, the Subcommittee noted that: 1. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 2. For the treatment of STI – Chlamydia and gonorrhea the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose (National STI guidelines) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/ 200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. This combination is not recommended for Urinary tract infection in any standard treatment guidelines. 3. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Theon Pharmaceuticals	Azithromycin Dihydrate IP eq. to Azithromycin anhydrous 250mg+ Cefixime trihydrate IP eq. to Anhydrous Cefixime 200mg film coated tablet	Indications mentioned are- Pharyngitis, Nasopharyngitis, Tracheitis, Acute bronchitis, Pneumonia, ENT infections, Uncomplicated gonorrhoea and UTI.	Not Submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. This combination is not as per standard therapeutic guidelines of RTI. 2. For the treatment of STI – Chlamydia and gonorrhea the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose (National STI guidelines) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/ 200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. 3. Cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. This combination is not recommended for Urinary tract infection in any standard treatment guidelines. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Magnet Lab	Azithromycin 125mg+ Cefixime 100mg tablets	Indicated for treatment of Typhoid and lower respiratory tract infection	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	Akums Drugs	Azithromycin IP as dihydrate eq. to anhydrous Azithromycin 500mg/ 250mg/ 125mg+ Cefixime IP as trihydrate eq. to anhydrous Cefixime 200mg/ 200mg/ 100mg film coated tablet and uncoated dispersible tablets	For treatment of MDR-Typhoid fever in adults, treatment of lower respiratory tract infections in adults	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Zuventus Healthcare	Azithromycin IP (as dihydrate) eq. to Anhydrous Azithromycin 250mg+ Cefixime IP (as trihydrate) eq. to Anhydrous Cefixime 200mg film coated tablets	Respiratory tract infections, gonorrhoea and associated infections,acute urinary tract infections, acute otitis media, helicobacter pylori infection,lyme disease, salmonella and shigella infections, cystic fibrosis, anti-inflammatory in COPD patients,In P. Falciparum malaria with other antimalarial drugs and typhoid fever.	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. For the treatment of STI – gonorrhea, the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose. (National STI guidelines) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. This combination is not recommended for Urinary tract infection or lyme disease in standard treatment guidelines. This combination is irrelevant for treatment of falciparum malaria & H. pylori infections. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of Ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	I. Indication as per package insert II. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Khandelwal Laboratories	Azithromycin IP as Dihydrate eq. to Anhydrous Azithromycin 250mg/ 500mg+ Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 200mg/ 200mg film caoted tablets	For treatment of resistant bacterial infections (at the direction of the physician) for indications such as – N. Gonorrhea, Community acquired pneumonia (CAP) and Multi-Drug Resistant Typhoid	It is indicated in Typhoid &Lower respiratory infection, Gonorrhea II. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. For the treatment of STI – gonorrhea, the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose. (National STI guidelines) whereas this FDC contains Azithromycin (250/ 500 mg)+ Cefixime (200/ 200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Ind-Swift Ltd.,	Cefixime IP as trihydrate eq. to Cefixime 200mg+ Azithromycin IP as Dihydrate Anhydrous eq. to Azithromycin 250mg film coated tablets	Cefixime: Lower respiratory tract infection pharyngitis and tonsillitis Acute Sinusitis, Gnorrhea and associated infections, Acute UTI, Lyme disease Azithromycin: Otitis Media, Respiratory Tract Infection, Cystic Fibrosis, Anti Inflammatory in COPD patient, Typhoid fever.	Not Submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. For the treatment of STI – Chlamydia and gonorrhea the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose. (National STI guidelines) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/ 200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. This combination is not recommended for Urinary tract infection or lyme disease in standard treatment guidelines. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Mankind Pharma	Cefixime IP as trihydrate eq. to Cefixime 200mg+ Azithromycin IP as Dihydrate Anhydrous eq. to Azithromycin 250mg film coated tablets	Typhoid and Lower respiratory tract infection	Respiratory tract infections Typhoid II. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Ozone Pharmaceuticals	Cefixime IP as trihydrate eq. to Cefixime 200mg+ Azithromycin IP as Dihydrate Anhydrous eq. to Azithromycin 250mg film coated tablets	Typhoid, RTI, PID, Gynaecological infections is a potent combination of macrolide and cephalosporin.	Not Submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. Mixed gynaecological infections is a nonspecific indication. Azithromycin and cefixime are not used in the management of common gynaecological conditions such as vaginal delivery, perineal tears, PROM, CS, septic abortion, pelvic surgeries, candidiasis, trichomoniasis and vaginosis. For the treatment of STI – Chlamydia and gonorrhea the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose. (National STI guidelines) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Mascot Healthcare	Cefixime IP 200mg+ Azithromycin IP 250mg film coated tablets	infections caused by. susceptible organisms, infections of the throat, pharyngitis and tonsillitis, community acquired pneumonia.	Indication of FDC not mentioned	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or RTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	Hetero Healthcare	Cefixime IP as trihydrate eq. to Cefixime100mg+ Azithromycin IP as Dihydrate Anhydrous eq. to Azithromycin 125mg uncoated dispersible tablets	Treatment of Respiratorytract infections both upper and lower RTIs, Multi Drug Resistant Typhoid fever	Not Submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or RTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Hetero Healthcare	Cefixime IP as trihydrate eq. to Cefixime 200mg+ Azithromycin IP as Dihydrate Anhydrous eq. to Azithromycin 250mg film coated tablets	Treatment of Respiratory tract infections both upper and lower RTIs, Multi Drug Resistant Typhoid fever	Not Submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or RTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	Aeon Formulations	Cefixime IP 200mg+ Azithromycin IP 250mg film coated tablets	Treatment of Community acquired Pneumonia	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. This combination is not as per standard therapeutic guidelines of RTI. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Zaneka Healthcare	Cefixime trihydrate IP 200mg/ 200mg+ Azithromycin dehydrate 250mg/ 500mg film coated tablets	U.R.T.I & L.R.T.I, Skin & Soft tissue infection	Not submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. This combination is not as per standard therapeutic guidelines of RTI. 2. This combination is not as per standard therapeutic guidelines of Skin and Soft tissue infections (ICMR, NCDC, IDSA) 3. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	Mascot Health	Cefixime 50mg + Azithromycin 100 mg per 5ml reconstituted suspension	infections caused by susceptible organisms, infections of the throat, pharyngitis and tonsillitis, community acquired pneumonia.	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or RTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	relax pharmaceuticals	Cefixime 200mg+ Azithromycin 500mg tablet	Typhoid and Lower respiratory tract infection	Respiratory tract infections Typhoid	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	relax pharmaceuticals	Cefixime 200mg+ Azithromycin 250mg tablet	Typhoid and Lower respiratory tract infection	Respiratory tract infections Typhoid	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	relax pharmaceuticals	Cefixime 200mg + Azithromycin 250mg film coated tablet	Used in respiratory track infection, Pharyngitis, Tonsilities, Anti-inflammatory, Salmonella and Shigella infection	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or RTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	Wallace	Cefixime 200mg + Azithromycin 250mg tablet	The company has recalled this FDC from the market and is no more marketing the same.	NA	-

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Alkem	Cefixime 200mg + Azithromycin 250mg tablet	Community acquired pneumonia.	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. This combination is not as per standard therapeutic guidelines of CAP 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. . 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	Alkem	Cefixime 100mg + Azithromycin 125mg tablet	Community acquired pneumonia.	i. Same as Annexure-A ii. Not approved	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. This combination is not as per standard therapeutic guidelines of CAP 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. . 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Legen Healthcare	Azithromycin (as dihydrate) eq. to Azithromycin IP 250mg/ 500mg+ Cefixime trihydrate eq. to Cefixime (Anhydrous) IP 200mg film coated tablet	RTI, SSTI, Typhoid fever	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Typhoid fever, RTI, Gonorrhoea, Upper repiratory tract ingection: pharyngitis/ tonsillitis, sinusitis, otitis media Lower respiratory tract infections: Bronchitis, acute exacerbation of chronic bronchitis, community acquired pneumonia of mild severity Sexually transmitted diseases: uncomplicated urethritis, uncomplicated cervicitis due to Neisseria gonorrhoeae or Chlamydia trachomatis Chancroid (genital ulcer disease in men), Skin and soft tissue infections: erysipelas, impetigo, secondary pyoderma, erythema migrains, Mycobacterial Infection ii.Not submitted.	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. For the treatment of STI – Chlamydia and gonorrhea the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose (National STI guidelines) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/ 200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. This combination is not mentioned for skin and soft tissue infections (ICMR, NCDC, IDSA) 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	DM Pharma	Azithromycin dihydrate IP eq. to anhydrous Azithromycin 250mg+ Cefixime trihydrate IP eq. to Cefixime (Anhydrous) IP 200mg film coated tablet	Upper and lower respiratory tract infections, urinary tract infection, gonorrhea	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Indicated for relief of symptoms for the treatment of bacterial infection caused by susceptible organism. 1. Respiratory tract infection 2. Urinary tract infection 3. Typhoid fever 4. Skin and soft tissue infections 5. Gonorrhoea ii.Not submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. For the treatment of gonorrhea the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose. (National STI guidelines, ICMR, NCDC) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Anglo-French Drugs	Azithromycin as Dihydrate eq. to anhydrous Azithromycin 250mg+ Cefixime trihydrate IP eq. to Cefixime anhydrous 200mg film coated tablet	Respiratory infection	i. Not submitted ii. Not submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. This combination is not as per standard therapeutic guidelines of RTI. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 752(E)	Azithromycin+ Cefixime	Combitic Global	Azithromycin Dihydrate IP eq. to Anhydrous Azithromycin 250mg+ Cefixime (As trihydrate) IP eq. to Anhydrous Cefixime	Not submitted	i.Not submitted. ii.Not submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or LRTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Corona Remedies	Azithromycin Dihydrate IP eq. to Anhydrous Azithromycin 250mg+ Cefixime (As trihydrate)•IP eq. to Anhydrous Cefixime 200mg film coated tablet	For treatment, control, prevention and improvement of following diseases, conditions and symptoms; Upper respiratory tract infections, Lower respiratory tract infections, UTI, Acute bacterial sinusitis, Acute bacterial otitis media, Pharyngitis and tonsillitis, Chronic bronchitis exacerbations, mild to moderate community acquired pneumonia, infections of Skin and skin structures Infection e.g. Folliculitis, cellulitis, erysipelas, uncomplicated Chlamydia trachomatis urethritis and cervicitis.	i.Not submitted. ii.Not submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. The combination of both the drugs in the treatment of RTI, UTI & Skin and soft tissue infections is not recommended by standard treatment guidelines. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. Mixed gynaecological infections is a nonspecific indication. Azithromycin and cefixime are not used in the management of common gynaecological conditions such as vaginal delivery, perineal tears, PROM, CS, septic abortion, pelvic surgeries, candidiasis, trichomoniasis and vaginosis (ICMR, CDC). For the treatment of STI – Chlamydia and gonorrhea the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose (National STI guidelines) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Wings Pharmaceuticals Pvt. Ltd	Azithromycin Dihydrate IP eq. to Anhydrous Azithromycin 250mg+ Cefixime (As trihydrate) IP eq. to Anhydrous Cefixime 200mg film coated tablet	Antibiotics	i) Indication mentioned in package insert does not match Annexure A. Indications mentioned in package insert are: Bronchitis, gonorrhoea, infection of ear, nose, tonsils etc. ii) Not submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. The combination of both the drugs in the treatment of RTI is not recommended by standard treatment guidelines. 2. For the treatment of STI – gonorrhea the Guidelines recommend the dosage of Azithromycin 1gm and cefixime 400mg single dose. (National STI guidelines, ICMR, NCDC) whereas this FDC contains Azithromycin (250/500 mg) + Cefixime (200/ 200 mg) strip of ten tablets (as stated at the time of hearing). Additionally, the CDC guidelines have expressed concern over the rising resistance to cefixime and hence recommend Ceftriaxone. 3. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 752(E)	Azithromycin+ Cefixime	Horizon Bioceutica ls'Pvt.	Azithromycin Dihydrate IP eq. to Anhydrous Azithromycin 250mg+ Cefixime (As trihydrate) IP eq. to Anhydrous Cefixime 200mg film coated tablet	Respiratory tract infections, Pharyngitis, Tonsilitis, Antiinflammatory, Salmonella and Shigella infections.	i. Same as Annexure-A ii. Not Submitted	This combination was discussed by "10 expert committee" on 11.06.2014. Their comments were as under: "This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval." The Subcommittee noted that: 1. Oral azithromycin and cefixime are both used individually in the treatment of typhoid fever. However, the duration of treatment of both the drugs differ. For typhoid fever, azithromycin is given for 5-7 days, while cefixime is given for 10 to 14 days. 2. Also, cefixime requires renally adjusted dosing whereas azithromycin does not, making it inappropriate for renally impaired patients. 3. This combination is not as per standard therapeutic guidelines of typhoid fever or RTI. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
48	S.O. 752(E)	Azithromycin+ Cefixime	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Lupin	Amoxicillin Trihydrate IP eq. To Amoxicillin 250mg + Dicloxacillin sodium IP eq. To Dicloxacillin 250mg hard gelatin capsule	Infection due to susceptible bacteria.	Not Submitted	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Navil Laboratories	Amoxicillin Trihydrate IP 250mg+ Dicloxacillin Sodium IP 250mg capsule	For the treatment of Upper RTIs, Lower RTIs, Genitourinary tract infections, Skin and skin structure infections.	i. Same as Annexure-A ii. Not approved	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin+ Dicloxacillin	Cipla Ltd.	Amoxicillin Trihydrate IP 250mg+ Dicloxacillin Sodium IP 250mg capsule	For the treatment of RTIs, UTI, Ottis media, Dental abscess, Septicaemia, Soft tissue infections and other bacterial infections due to beta-lactamase producing bacteria.	i. Same as Annexure-A ii. Not approved	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Akums Drugs	Amoxicillin Trihydrate IP 250mg+ Dicloxacillin Sodium IP 250mg capsule	RTI, UTI, media, dental abscess, soft-tissue infection and other bacterial infection due to beta-lactamase producing organisms.	i. Same as Annexure-A ii. Not approved	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Theon Pharmaceuticals	Amoxycillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg tablets	RTI, UTI, Skin and soft tissue infections, Bone infections, Serious Infection	Not Submitted	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Ind-Swift Ltd.,	Amoxycillin Trihydrate IP eq. to Amoxycillin 2500mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg capsules	Respiratory tract Infections- tonsillar abscess, ottis media, suppurative sinus infection, acute and chronic bronchitis, bronchi-ectasis, bronchopneumonia, Pleurisy, emphysema, bronchitis Gynaecological infections- Septic abortion, puerperal infections, caesarean sections and gynaeco-logical surgeries. Urinary Tract Infections- Acute and Chronic pyelonephritis, Cystitis, urethritis Skin and Soft tissue infections- Recurrent boils, Carbuncles, impetigo, cellulitis, and other infected dermatosis.	i. Same as Annexure-A ii. Not approved	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package Insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Akums Drugs	Amoxycillin Trihydrate IP eq. to Amoxycillin 125mg+ Dicloxacillin Sodium USP eq. to Dicloxacillin 125mg uncoated dispersible tablets	RTI, UTI, media, Skin and soft-tissue infection, Bone infection and serious infections.	i. Same as Annexure-A ii. Not approved	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Micro Laboratories	Amoxycillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg Capsules	Indicated for the treatment of adult patients with infections caused by susceptible microorganism in ENT infection, skin and soft tissue and Lower RTI.	i. Same as Annexure-A ii. Not approved	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of Ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Jenburkt Pharmaceuticals	Amoxicillin Trihydrate IP eq. to Amoxycillin 125mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 125mg uncoated dispersible tablet	Infections caused by pathogens susceptible to Amoxicillin and Dicloxacillin including Lower respiratory tract infections caused by penicillinase producing Staphycocci which have demonstrated susceptibility to the drug	i. Same as Annexure-A ii. Not approved	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Uni Medicolabs	Amoxicillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg hard gelatin capsule	RTI, UTI, Skin and soft tissue infections, Bone infections, Serious Infection, Gynaecological infections	Respiratory Tract Infections Tonsillar abscess, otitis media, suppurative sinus infection, acute chronic bronchitis, bronchiectasis, bronchopneumonia, pleurisy, empyema, lung abscess, emphysema, bronchiolitis. Urinary Tract Infections Acute and chronic pyelonephritis, cystitis, urethritis. Skin and Soft Tissue Infections Recurrent boils, carbuncles, impetigo, cellulitis and other infected dermatoses. Bone Infections Osteomyelitis and septic arthritis. Serious Infections Septicaemia, bacterial endocarditis, brain abscess and bacterial meningitis.	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Skymap Pharmaceuticals	Amoxicillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg uncoated dispersible tablet	Respiratory tract infection, urinary tract infection, skin & soft tissue infection, bone infection, serious infection :septicaemia, bacterial endocarditis, barin abscess & bacterial meningitis.	Not Submitted	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Comed Chemicals	Amoxicillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg capsule	Impacted teeth, tooth extraction, Cervicitis,Urethritis, U.R.T.I, L.R.T.I	i. Same as Annexure-A ii. Not approved	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of Ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Skymap Pharmaceutical	Amoxicillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg hard gelatin capsule	Antibiotic	Not Submitted	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Skymap Pharmaceutical	Amoxicillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg hard gelatin capsule	Antibiotic	Not Submitted	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Skymap Pharmaceutical	Amoxicillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg hard gelatin capsule	Antibiotic	Not Submitted	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 753(E)	Amoxicillin +Dicloxacillin	Meridian Medicare	Amoxicillin 250mg+ Dicloxacillin 250mg	Respiratory Tract infections, Gynaecological infections, UTI, SSTI, Bone infections, septicaemia, bacterial endocarditis, brain abscess, and bacterial meningitis.	i.Not submitted. ii.Not submitted	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin + Dicloxacillin	Laborate Pharmaceuticals India Limited	Amoxicillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg hard gelatin capsule	Infections caused by susceptible bacteria, skin infection, Pneumonia, UTI, RTI, Septicaemia	i. Indications mentioned in package insert is different from Annexure A. Indicationes mentioned in pack insert are: Respiratory tract infections: Tonsillar abscess, otitis media, suppurative sinus infection, acute chronic bronchitis, bronchiectasis, bronchopneumonia, pleurisy, empyema, lung abscess, emphysema, bronchiolitis Urinary tract infection: Acute and chronic pyelonephritis, cystitis, urethritis. Skin and soft tissue infections: Recurrent boils, carbuncles, impetigo, cellulitis and other infected dermatoses Bone infections: Osteomyelitis and septic arthritis Serious infections: Septicaemia, bacterial endocarditis, brain abscess and bacterial meningitis. ii. NA	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 753(E)	Amoxicillin + Dicloxacillin	Wings Pharmaceuticals Pvt. Ltd	Amoxicillin Trihydrate IP eq. to Amoxycillin 250mg+ Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg hard gelatin capsule	Not mentioned	i. Indications mentioned in package insert is : RTI Tonsilar abscess, otitis media, suppurative sinus infection, acute chronic bronchitis, bronchiectasis, bronchopneumonia, pleurisy, empyema, lung abscess, emphysema, bronchiolitis UTI, acute and chronic pyelonephritis, cystitis and other infected dermatoses, bone infections, osteomyelitis and septic arthritis, serious infections, septicaemia, bacterial endocarditis, brain abscess and bacterial meningitis. ii. NA	It was noted by the Subcommittee that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in year 2006. The Subcommittee noted that: 1. Amoxicillin is an aminopenicillin which has extended spectrum when compared to penicillin but it is not effective in presence of penicillinase whereas dicloxacillin has same spectrum as that of penicillin but it is resistant to penicillinase. So, amoxicillin is inactive against staphylococcus which elaborate beta lactamases while dicloxacillin is effective mainly for MSSA and has narrower spectrum. Therefore, depending on situation only one drug may be required. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
49	S.O. 753(E)	Amoxicillin + Dicloxacillin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 754(E)	Amoxicillin 250 mg+ Potassium Clavulanate Diluted 62.5 mg	-	-	-	-	The Subcommittee noted the recommendations of previous committee. The Subcommittee further noted that following formulations suitable for children are approved by the DCGI: 1. Each 5ml of reconstituted suspension contains: Amoxycillin trihydrate IP e.q. to Amoxycillin 200 mg Caluvulanate Potassium e.q. to Clavulanic acid 28.5 mg 2. Each uncoated dispersible tablet contains: Amoxycillin trihydrate IP e.q. to anhydrous Amoxycillin 250 mg/125 mg Caluvulanate Potassium e.q. to Clavulanic acid 62.5 mg/31.25mg 3. Each 5 ml reconstituted syrup contains: Amoxycillin as trihydrate 125mg + Clavulanic Acid 31.25mg as potassium salt suspension. The Subcommittee examined and considered that FDC Amoxicillin 250 mg+Potassium Clavulanate Diluted 62.5 mg for suspension is also acceptable and rational.
50	S.O. 754 (E)	Amoxicillin 250 mg+ Potassium Clavulanate Diluted 62.5 mg	**The Subcommittee examined and considered that FDC Amoxicillin 250 mg+Potassium Clavulanate Diluted 62.5 mg for suspension is acceptable and rational. Therefore, this FDC of Amoxicillin 250 mg+Potassium Clavulanate Diluted 62.5 mg (for suspension) should not be prohibited under section 26A.**				

ml

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 755(E)	Azithromycin + Levofloxacin	Akums Drugs	Azithromycin 250mg/ 500mg + Levofloxacin 250mg/ 500mg film coated tablet	treatment of adults with respiratory tract, skin infection/ skin urinary tract infections	i. Acute bacterial sinusitis. Pharyngitis, tonsillitis, acute bacterial exacerbation of nosocomial pneumonia, community acquired pneumonia, complicated and uncomplicated skin and soft tissue infections, complicated & uncomplicated urinary tract infections, acute pyelonephritis, chronic bacterial prostatiits, inhalational anthrax. ii. Not approved	1. This combination is not as per standard therapeutic guidelines (National or International) in management of Community Acquired Pneumonia (CAP) and other indications mentioned by the company. 2. Levofloxacin dose needs to be adjusted in renally impaired patients (CrCl <50 mL/min) while azithromycin does not, making the combination product inappropriate for patients with renal impairment. 3. Fluoroquinolones such as Levofloxacin are an integral part of MDR-TB therapy and should not be used in combination for other indications. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 755(E)	Azithromycin + Levofloxacin	Hetero Healthcare	Azithromycin Dihydrate IP eq. To Anhydrous Azithromycin 250 mg/ 500mg + Levofloxacin 250mg/ 500mg film caoted tablets	Respiratory Tract Infection (both upper and lower RTIs)	Not Submitted	1. This combination is not as per standard therapeutic guidelines (National or International) in management of Community Acquired Pneumonia (CAP) and other indications mentioned by the company. 2. Levofloxacin dose needs to be adjusted in renally impaired patients (CrCl <50 mL/min) while azithromycin does not, making the combination product inappropriate for patients with renal impairment. 3. Fluoroquinolones such as Levofloxacin are an integral part of MDR-TB therapy and should not be used in combination for other indications. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 755(E)	Azithromycin + Levofloxacin	Macleods Pharmaceuticals	Levofloxacin Hemihydrate IP eq. to Levofloxacin 250mg/ 500mg+ Azithromycin Dihydrate IP eq. to Anhydrous Azithromycin 250mg/ 500mg film coated tablets	Treatment of respiratory tract infections	i. Same as Annexure-A ii. Not approved	1. This combination is not as per standard therapeutic guidelines (National or International) in management of Community Acquired Pneumonia (CAP) and other indications mentioned by the company. 2. Levofloxacin dose needs to be adjusted in renally impaired patients (CrCl <50 mL/min) while azithromycin does not, making the combination product inappropriate for patients with renal impairment. 3. Fluoroquinolones such as Levofloxacin are an integral part of MDR-TB therapy and should not be used in combination for other indications. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

124

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 755(E)	Azithromycin + Levofloxacin	Pure & Cure Healthcare	Azithromycin Dihydrate IP 250mg+ Levofloxacin Hemihydrate IP 250mg film coated tablet	Pneumonia, upper respiratory tract infections and bronchitis	Not Submitted	1. This combination is not as per standard therapeutic guidelines (National or International) in management of Community Acquired Pneumonia (CAP) and other indications mentioned by the company. 2. Levofloxacin dose needs to be adjusted in renally impaired patients (CrCl <50 mL/min) while azithromycin does not, making the combination product inappropriate for patients with renal impairment. 3. Fluoroquinolones such as Levofloxacin are an integral part of MDR-TB therapy and should not be used in combination for other indications. 4. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
51	S.O. 755(E)	Azithromycin + Levofloxacin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 756(E)	Cefixime + Linezolid	Alkem	Cefixime 200mg+ Linezolid 600mg film coated tablet	Community acquired pneumonia	i. Indications mentioned in package insert do not match as above. Package insert mentions: Community acquired pneumonia, Complicated skin and skin structure infections, including diabetic foot infections; osteomyelitis & compound fractures, cuased by Gram positive [Staphylococcus aureus (methicillin- susceptible and resistant strains), Streptococcus pyogenes, or streptococcus agalactiae] and suspected Gram- H53negative pathogens ii. Not approved	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotics and will drive selection of resistant strains. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 756(E)	Cefixime + Linezolid	Macleods	Cefixime IP eq. To Anhydrous Cefixime 200mg+ Linezolid IP 600mg film coated tablet	Indicated for the treatment of Respiratory tract infection and skin and soft tissue infections.	i. Same as Annexure-A ii. Not approved	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotics and will drive selection of resistant strains. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 756(E)	Cefixime + Linezolid	Aristo	Cefixime IP (as trihydrate) eq. To Cefixime Anhydrous 200mg+ Linezolid IP 600mg film coated tablet	In poly-microbial infections in adults caused by susceptible gram positive bacteria & gram negative bacteria: Complicated skin and skin structure infections: Diabetic foot infections, purulent cellulitis, major abscesses, surgical site infections, Community acquired pneumonia, Bone & joint infections : osteomyelitis, Prosthetic joint infections.	i. Same as Annexure-A ii. Not approved	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotics and will drive selection of resistant strains. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 756(E)	Cefixime + Linezolid	Kusum	Cefixime IP as Trihydrate eq. To Anhydrous Cefixime 200mg + Linezolid IP 600mg	1. Pneumonia 2. Skin and soft tissue infection.	i. Same as Annexure-A ii. Not approved	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotic and will drive selection of resistant strains. 5.The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 756(E)	Cefixime + Linezolid	Hetero Labs	Cefixime 200mg + Linezolid 600mg tablets	Antibacterial drug	1. Lower respiratory tract infections including bronchitis, nosocomial pneumonia, community acquired pneumonia 2. Complicated urinary tract infections including cystitis, cytourethritis, pyelonephritis. 3. Complicated skin and soft tissue infections. ii. Not approved	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotics and will drive selection of resistant strains. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 756(E)	Cefixime + Linezolid	Micro Labs	Cefixime IP (as trihydrate) eq. to Cefixime 200mg+ Linezolid IP 600mg tablets	Treatment of respiratory tract infections	i. Same as Annexure-A ii. Not approved	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotics and will drive selection of resistant strains. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 756(E)	Cefixime + Linezolid	Hetero Labs	Cefixime IP (as trihydrate) eq. to Cefixime 200mg+ Linezolid IP 600mg film coated tablets	Complicated skin and skin structure infections, including diabetic foot infections. Osteomyelitis & Compound fracture, caused by Gram-positive Staphylococcus (methillin-susceptible and resistant strains), Streptococcus pyrogens or Streptococcus agalactiae and suspected gram-negative pathogens. Vancomycin-Resistant Enteroccusfaecium infections. Noscomial pneumonia. Uncomplicated SSTIs.	Not Submitted	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotics and will drive selection of resistant strains. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 756(E)	Cefixime + Linezolid	Akums Drugs	Cefixime IP as trihydrate eq. to Anhydrous Cefixime 200mg+ Linezolid 600mg filmcoated tablet	Soft skin tissue infection, UTI, RTI, Typhoid fever, Bone & joint infection.	i. Same as Annexure-A ii. Not approved	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotics and will drive selection of resistant strains. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 756(E)	Cefixime + Linezolid	Zaneka Healthcare	Cefixime Trihydrate IP eq. to cefixime anhydrous 200mg+ Linezolid IP 600mg film coated tablet	Nosocomial pneumonia, community acquired pneumonia, complicated skin and skin structure infection and diabetes foot infection without concomitant osteomylitis	Not Submitted	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotics and will drive selection of resistant strains. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 756(E)	Cefixime + Linezolid	Comed Chemicals	Cefixime Trihydrate IP eq. to cefixime anhydrous 200mg+ Linezolid IP 600mg film coated tablet	Osteomyletis, Post operative Conditions, Cellulitis, Abscess, Diabetic foot ulcer, Soft tissue infections	i. Same as Annexure-A ii. Not approved	1. This combination is not mentioned in standard guidelines for the indications mentioned by the company. 2. Linezolid has been recently categorized as one of RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). Hence, these antibiotics are not ideal to be formulated as combination product. 3. Cefixime belongs to 'Watch group' as per WHO EML list. 4. Linezolid is useful mainly in severe infections due to gram positive organisms (such as severe MRSA infections etc) whereas Cefixime is broad spectrum and acts mainly on gram negative and few gram-positive organisms. Combination will promote misuse of antibiotics and will drive selection of resistant strains. 5. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
52	S.O. 756(E)	Cefixime + Linezolid	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 757(E)	Amoxicillin + Cefixime + Potassium Clavulanic Acid	Akums Drugs	Amoxicillin 500mg+ Cefixime IP as Trihydrate eq. To Anhydrous Cefixime 200mg+ Potassium Clavulanate IP (as Potassium Clavulanate Diluted IP) eq. To Clavulanic Acid 125mg film coated tablet	Cefixime clavulanate & Amoxycillin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.	i. For the treatment of lower respiratory infection, Urinary tract infection, Bronchitis, Pharyngitis, Otitis media & uncomplicated Gonorrhoea ii. Not approved	1. Subcommittee noted that Cefixime requires OD/BD dosing whereas, Amoxicillin dosing is TDS/QDS. When these two drugs are given in combination, it will have a pharmacokinetic mismatch. 2. Amoxicillin/clavulanic acid combination extends the antibiotic spectrum of amoxicillin to include many beta-lactamase producing organisms. Cefixime is a 3rd generation cephalosporin antibiotic, highly stable in the presence of beta-lactamase enzymes. Hence combining the two in FDC does not add to the anti-bacterial spectrum. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. The combination of the drugs in the treatment of indications mentioned by the company has not recommended by any standard guidelines.
53	**S.O. 757(E)**	**Amoxicillin + Cefixime + Potassium Clavulanic Acid**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Lupin	Ofloxacin 50mg+ Nitazoxanide 100mg per 5ml oral suspension	For diarrhoea of mixed infection. During the hearing, the appellant stated that this FDC is indicated for adults above 12 years.	i) Not submitted ii) Not submitted	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Lupin	Ofloxacin IP 200mg+ Nitazoxanide 500mg film coated tablet	for diarrhoea of mixed infection,	i) The firm has mentioned indications in package insert as: - For the treatment of enterocolitis/ urogential infections and other susceptible infections in adult patients only ii) Not submited	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Mankind	Ofloxacin IP 50mg+ Nitazoxanide 100mg per 5ml Reconstituted suspension	for diarrhoea, dysentery and rotavirus induced diarrhoea. (For children above 1 year)	i) same as annexure A ii) Not submited	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Akums Drugs	Ofloxacin 50mg+ Nitazoxanide 100mg per 5ml Reconstituted suspension	for treatment of infectious diarrhoea caused by cryptosporidium parvum& giardia lamblia in patients of 1 year and above and bacterial infections of ear & urinary tract.	i) same as annexure A ii) Not submited	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Ind Swift	Ofloxacin USP 200mg+ Nitazoxanide 500mg film coated tablet	Indications for Ofloxacin-Bronchitis,pneumonia,UTI,bone and joint infections intra-abdominal infections,gonorrhoea ENTinfections,skin and soft tissue infections,typhoidfever,otitis gynaecological infections,urethritis cervicitis. Indications for Nitazoxanide Helminthiasis,giardiasis,amoebiasis, trichomoniasis,fasciolasis,cryptospo ridiosis.	i) Not submitted ii) Not submitted	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Lifestar Pharma	Ofloxacin 50mg+ Nitazoxanide 100mg oral suspension	for diarrhoea, dysentery and rotavirus induced diarrhoea.(For children above 1 year)	i) same as annexure A ii) Not submited	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Akums Drugs	Ofloxacin USP 200mg+ Nitazoxanide 500mg film coated tablet	For the treatment of enterocolitis/ urogential infections and other susceptible infections in adult patients only.	i) same as annexure A ii) Not submited	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Ind-Swift Ltd.,	Ofloxacin 100mg+ Nitazoxanide USP 50mg per 5ml syrup	for treatment of infectious diarrhoea caused by cryptosporidium parvum and girdialamblia. It is useful in certain kinds of bacterial infections such as urinary tract infections.	i) Not submitted ii) Not submitted	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Mascot Healthcare	Ofloxacin 50mg+ Nitazoxanide USP 100mg per 5ml suspension	For soft tissue infections, GI infections, Urinary Tract Infection, Gonorrhoea, Cryptosporidiosis	i) same as annexure A ii) Not submited	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Windlas Biotech	Ofloxacin 50mg+ Nitazoxanide 100mg oral suspension	For treatment of variety of bacterial infections and top treat diarrhoea due to certain intestinal parasitic infections (i.e, Cryptosporidiuparvum and Giardia lamblia) including urogenital infection in adults	i) For treatment of variety of bacterial infections and top treat diarrhoea due to certain intestinal parasitic infections (i.e, Cryptosporidiuparvum and Giardia lamblia) ii)Not provided	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 758(E)	Ofloxacin + Nitazoxanide	JK Print Packs	Ofloxacin USP 50mg+ Nitazoxanide 100mg oral suspension	Diarrhoea, Dysentery, Rotavirus induced Diarrhoea	i) same as annexure A ii) Not submited	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Horizon Bioceuticals	Ofloxacin USP 200mg+ Nitazoxanide 500mg film tablet	Antibacterial and Anti-protozoal	i) same as annexure A ii) Not submited	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 758(E)	Ofloxacin + Nitazoxanide	DM Pharma	Ofloxacin IP 50mg+ Nitazoxanide IP 125mg per 5ml syrup	Ear infections, urinary tract infections, Giardiasis.	i)Anti parasitic and antibacterial medication used in the treatment of diarrhea. It is also useful for treating certain kinds of bacterial infections (ear infections, urinary tract infections) it also shows better effects in the treatment of chronic hepatitis B. ii) Not submitted	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 758(E)	Ofloxacin + Nitazoxanide	Meridian Medicare	Ofloxacin USP 50mg+Nitazoxanide 100mg dry syrup	The Medication is used to treatdiarrhea caused by certain paracite infections of the intestines(Cryptosporidiumparvum and Giardia lamblia).	i) Not submitted ii) Not submitted	The Subcommittee noted that FDC of Nitazoxanide (500mg) + Ofloxacin (200mg) Tablet is approved by DCGI on 30.06.2005 for the treatment of Enterocolitis/ Urogenital infections and other susceptible infections in adults patients only. The Subcommittee noted that: 1. The ingredients have different therapeutic indications. Having diarrhoea of mixed infection (bacterial, parasitic, viral) is rare. 2. This combination is not as per standard therapeutic guidelines of diarrhoea. 3. Patients may not need both the ingredients and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. This FDC will enhance risk of antimicrobial resistance. 4. There is safety concern with Fluoroquinolones in paediatric patients and suspension formulation may be misused in this age group. There is no convincing scientific/ clinical evidence/ justification for the FDC.
54	S.O. 758(E)	Ofloxacin + Nitazoxanide	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation::** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	Macleods	Cefpodoxime Proxetil IP eq. To Anhydrous Cefpodoxime 200mg+ Levofloxacin hemihydrate IP eq. To Levofloxacin 250mg film coated tablet	It is indicated for the treatment of respiratory tract infection	i. Same as Annexure-A ii. Not approved	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	Lupin	Cefpodoxime Proxetil IP eq. To Anhydrous Cefpodoxime 200mg+ Levofloxacin hemihydrate IP eq. To Levofloxacin 250mg film coated tablet	Infection due to susceptible bacteria.	i. Same as Annexure-A ii. Not approved	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	Hetero Labs	Cefpodoxime Proxetil 200mg + Levofloxacin 250mg tablets	anti-bacterial drug.	i. Package insert differs in indication from above: Upper respiratory tract infections, Lower respiratory tract infections, Complicated urinary tract infections, complicated skin an skin structure infections ii. Not approved	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	Mankind Pharma	Cefpodoxime Proxetil IP eq. to Anhydrous Cefpodoxime 200mg+ Levofloxacin Hemihydrate IP eq. to Levofloxacin 250mg film coated tablet	for the treatment of respiratory tract infections	i. Same as Annexure-A ii. Not approved	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	Theon Pharmaceuticals	Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg+ Levofloxacin Hemihydrate IP eq. to Levofloxacin 250mg film coated tablets	treatment of bronchitis, pneumonia & sinus	Not Submitted	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	Malik Lifesciences	Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg+ Levofloxacin Hemihydrate IP eq. to Levofloxacin 250mg film coated tablets	formulated for the indicated in the following infections caused by organisms susceptible to cefpodoxime and/ or Levofloxacin:- moderate to severe respiratory infections like community acquired pneumonia, acute exacerbation of chronic bronchitis, etc. Enteric fever, UTI	i. Same as Annexure-A ii. Not approved	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	Mascot Healthcare	Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg+ Levofloxacin Hemihydrate IP eq. to Levofloxacin 250mg film coated tablets	bacterial infection, skin infection, plague.	Indication mentioned in package insert is different from above. Package insert indication: 1. Pneumonia, bronchitis & other respiratory tract infection 2. Sinusitis 3.Urinary tract & genital tract infections 5.Gonorrhoea & rectal gonococcal infections 5.Skin infections 6.Otitis media 7.Tonsilitis, Pharyngitis ii. Not approved	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	Akums Drugs	Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg+ Levofloxacin Hemihydrate IP eq. to Levofloxacin 250mg film coated tablets	used in the treatment of soft tissue infection, lower and upper respiratory tract infections and other infections	i. Indication given in PPT which is different from above as: Moderate to severe respiratory infections like community-acquired pneumonia, acute exacerbation of chronic bronchitis, etc. Enteric fever, UTI. ii. Not approved	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	relax pharmaceuticals	Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg+ Levofloxacin Hemihydrate IP eq. to Levofloxacin 250mg film coated tablets	Used in treatment respiratory tract infections.	i. Same as Annexure-A ii. Not approved	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	Corona Remedies	Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg + Levofloxacin Hemihydrate IP eq. to Levofloxacin 250mg film coated tablets	It is used to treat mixed bacterial infections. It stops bacteria from spreading. It is used to treat disease such as bronchitis (infections of the air passages to the lungs), gonorrhoea (a sexually transmitted disease) and infections of ear, nose, throat, tonsils and urinary tract.	i.Not submitted. ii.Not submitted	The "10 expert committee report stated that IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDCand the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance". Subcommittee agreed with above comments. Further, it noted that 1. Levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for other indications. 2. There is dosage frequency mismatch- for RTI Levofloxacin is given 500mg/750mg once daily whereas Cefpodoxime is 200 mg given twice a day. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
55	S.O. 759(E)	Cefpodoxime Proxetil + Levofloxacin	**The Subcommittee is of the opinion that:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 760(E)	Combikit of Azithromycin dihydrate, secnidazole and fluconazole	Hetero	Combikit of Azithromycin dihydrate eq. To 1g of anhydrous Azithromycin, secnidazole 1g and fluconazole 150mg film coated tablet	Syndromic management of vaginal discharge.	i. Same as Annexure-A ii. Not approved	Subcommittee noted that this FDC of Combipack of 1 tablet of Fluconazole 150mg ,1 film coated tablet of Azithromycin dihydrate eq. to Azithromycin 1gm & 2 film coated tabletof Secnidazole 1gm was approved by DCGI on 07.06.1999. The Subcommittee noted that: 1. The three diseases most frequently associated with vaginal discharge are Bacterial vaginosis, T. vaginalis infection and candidiasis. (CDC STD Treatment guidelines). There is no role of azithromycin in the treatment any of these infections. 2. For the syndromic management of vaginal discharge, the National Guidelines on Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted Infections (July 2014) recommend: Tab. Secnidazole 2 gm orally, single dose (OR Tab. Tinidazole 500 mg orally, twice daily for 5 days OR Tab. Metronidazole 400 mg, twice daily for 7 days) Plus Tab Fluconazole 150mg orally single dose OR local Clotrimazole 500 mg vaginal pessary once. Azithromycin is not mentioned here. The National & International Standard Treatment guidelines for the management of PID, the anti-microbial combination recommended are Ceftriaxone+ Doxycycline ± Metronidazole and for the vaginal discharge Tinidazole + Clindamycin + Fluconazole. Azithromycin is not mentioned as combination therapy in both of the above conditions. Azithromycin is mentioned for the use in Cervicitis/ Urethritis/ Mucopurulent Gonococcal in combination with Ceftriaxone. 3. The combination of the three drugs in the treatment of indications mentioned by the company is not recommended by standard therapeutic guidelines. The combikit of Fluconazole tablet, Azithromycin tablet and Ornidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. The above combikit is similar in nature and hence should be considered in the same category as already considered irrational by the DTAB. There is no convincing scientific/ clinical evidence/ justification for the combikit.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 760(E)	Combikit of Azithromycin dihydrate, secnidazole and fluconazole	Akums Drugs	Combikit of Azithromycin dihydrate, secnidazole 1gm and fluconazole 150mg	For treatment of mixed vaginal infections or as empirical cure of suspected mixed vaginal infections such as vulvovaginitis, bacterial vaginosis and trichomoniasis; it is also indicated in syndromic management of pelvic inflammatory disease,	i. Same as Annexure-A ii. Not approved	Subcommittee noted that this FDC of Combipack of 1 tablet of Fluconazole 150mg ,1 film coated tablet of Azithromycin dihydrate eq. to Azithromycin 1gm & 2 film coated tabletof Secnidazole 1gm was approved by DCGI on 07.06.1999. The Subcommittee noted that: 1. The three diseases most frequently associated with vaginal discharge are Bacterial vaginosis, T. vaginalis, and candidiasis. (CDC STD Treatment guidelines). There is no role of azithromycin in the treatment any of these infections. 2. For the syndromic management of vaginal discharge, the National Guidelines on Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted Infections (July 2014) recommend: Tab. Secnidazole 2 gm orally, single dose (OR Tab. Tinidazole 500 mg orally, twice daily for 5 days OR Tab. Metronidazole 400 mg, twice daily for 7 days) Plus Tab Fluconazole 150mg orally single dose OR local Clotrimazole 500 mg vaginal pessary once. Azithromycin is not mentioned here. The National & International Standard Treatment guidelines for the management of PID, the anti-microbial combination recommended are Ceftriaxone + Doxycycline ± Metronidazole and for the vaginal discharge Tinidazole + Clindamycin + Fluconazole. Azithromycin is not mentioned as combination therapy in both of the above conditions. Azithromycin is mentioned for the use in Cervicitis/ Urethritis/ Mucopurulent Gonococcal in combination with Ceftriaxone. 3. The combination of the three drugs in the treatment of indications mentioned by the company is not recommended by standard therapeutic guidelines. The combikit of Fluconazole tablet, Azithromycin tablet and Ornidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. The above combikit is similar in nature and hence should be considered in the same category as already considered irrational by the DTAB. There is no convincing scientific/ clinical evidence/ justification for the combikit.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 760(E)	Combikit of Azithromycin dihydrate, secnidazole and fluconazole	Acme Generics	Combikit of Azithromycin dihydrate 1000mg, secnidazole 1gm and fluconazole 150mg	The kit is recommended in the syndromic management of vaginal discharge due to candidiasis, bacterial vaginosis, trichomoniasis, chlamydial infections or due to mixed infection caused by these organisms.	i. Same as Annexure-A ii. Not approved	Subcommittee noted that this FDC of Combipack of 1 tablet of Fluconazole 150mg ,1 film coated tablet of Azithromycin dihydrate eq. to Azithromycin 1gm & 2 film coated tabletof Secnidazole 1gm was approved by DCGI on 07.06.1999. The Subcommittee noted that: 1. The three diseases most frequently associated with vaginal discharge are Bacterial vaginosis, T. vaginalis, and candidiasis. (CDC STD Treatment guidelines). There is no role of azithromycin in the treatment any of these infections. 2. For the syndromic management of vaginal discharge, the National Guidelines on Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted Infections (July 2014) recommend: Tab. Secnidazole 2 gm orally, single dose (OR Tab. Tinidazole 500 mg orally, twice daily for 5 days OR Tab. Metronidazole 400 mg, twice daily for 7 days) Plus Tab Fluconazole 150mg orally single dose OR local Clotrimazole 500 mg vaginal pessary once. Azithromycin is not mentioned here. The National & International Standard Treatment guidelines for the management of PID, the anti-microbial combination recommended are Ceftriaxone + Doxycycline ± Metronidazole and for the vaginal discharge Tinidazole + Clindamycin + Fluconazole. Azithromycin is not mentioned as combination therapy in both of the above conditions. Azithromycin is mentioned for the use in Cervicitis/ Urethritis/ Mucopurulent Gonococcal in combination with Ceftriaxone. 3. The combination of the three drugs in the treatment of indications mentioned by the company is not recommended by standard therapeutic guidelines. The combikit of Fluconazole tablet, Azithromycin tablet and Ornidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. The above combikit is similar in nature and hence should be considered in the same category as already considered irrational by the DTAB. There is no convincing scientific/ clinical evidence/ justification for the combikit.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 760(E)	Combikit of Azithromycin dihydrate, secnidazole and fluconazole	Coral Laboratories	Kit Contains: 1Tab Fluconazole 150mg+1 Tab Azithromycin 1gm+2 tablets of Secnidazole 1gm	Sexually transmitted disease, infective leucorrhoea, bacterial vaginitis, trichomonas vaginitis, pelvic inflammatory disease, venereal disease	i. It is indicated for the syndromic management of vaginal discharge. ii. Not approved	Subcommittee noted that this FDC of Combipack of 1 tablet of Fluconazole 150mg ,1 film coated tablet of Azithromycin dihydrate eq. to Azithromycin 1gm & 2 film coated tabletof Secnidazole 1gm was approved by DCGI on 07.06.1999. The Subcommittee noted that: 1. The three diseases most frequently associated with vaginal discharge are Bacterial vaginosis, T. vaginalis, and candidiasis. (CDC STD Treatment guidelines). There is no role of azithromycin in the treatment any of these infections. 2. For the syndromic management of vaginal discharge, the National Guidelines on Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted Infections (July 2014) recommend: Tab. Secnidazole 2 gm orally, single dose (OR Tab. Tinidazole 500 mg orally, twice daily for 5 days OR Tab. Metronidazole 400 mg, twice daily for 7 days) Plus Tab Fluconazole 150mg orally single dose OR local Clotrimazole 500 mg vaginal pessary once. Azithromycin is not mentioned here. The National & International Standard Treatment guidelines for the management of PID, the anti-microbial combination recommended are Ceftriaxone + Doxycycline ± Metronidazole and for the vaginal discharge Tinidazole + Clindamycin + Fluconazole. Azithromycin is not mentioned as combination therapy in both of the above conditions. Azithromycin is mentioned for the use in Cervicitis/ Urethritis/ Mucopurulent Gonococcal in combination with Ceftriaxone. 3. The combination of the three drugs in the treatment of indications mentioned by the company is not recommended by standard therapeutic guidelines. The combikit of Fluconazole tablet, Azithromycin tablet and Ornidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. The above combikit is similar in nature and hence should be considered in the same category as already considered irrational by the DTAB. There is no convincing scientific/ clinical evidence/ justification for the combikit.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 760(E)	Combikit of Azithromycin dihydrate, secnidazole and fluconazole	Pure & Cure Healthcare	Combikit of Azithromycin dihydrate IP eq. to Azithromycin anhydrous 1gm, secnidazole IP 1gm and fluconazole IP 150mg	Syndromic management of genital infections, trichomoniasis, infection or mixed with Chlamydia and neisseria	i. Same as Annexure-A ii. Not approved	Subcommittee noted that this FDC of Combipack of 1 tablet of Fluconazole 150mg ,1 film coated tablet of Azithromycin dihydrate eq. to Azithromycin 1gm & 2 film coated tabletof Secnidazole 1gm was approved by DCGI on 07.06.1999. The Subcommittee noted that: 1. The three diseases most frequently associated with vaginal discharge are Bacterial vaginosis, T. vaginalis, and candidiasis. (CDC STD Treatment guidelines). There is no role of azithromycin in the treatment any of these infections. 2. For the syndromic management of vaginal discharge, the National Guidelines on Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted Infections (July 2014) recommend: Tab. Secnidazole 2 gm orally, single dose (OR Tab. Tinidazole 500 mg orally, twice daily for 5 days OR Tab. Metronidazole 400 mg, twice daily for 7 days) Plus Tab Fluconazole 150mg orally single dose OR local Clotrimazole 500 mg vaginal pessary once. Azithromycin is not mentioned here. The National & International Standard Treatment guidelines for the management of PID, the anti-microbial combination recommended are Ceftriaxone + Doxycycline ± Metronidazole and for the vaginal discharge Tinidazole + Clindamycin + Fluconazole. Azithromycin is not mentioned as combination therapy in both of the above conditions. Azithromycin is mentioned for the use in Cervicitis/ Urethritis/ Mucopurulent Gonococcal in combination with Ceftriaxone. 3. The combination of the three drugs in the treatment of indications mentioned by the company is not recommended by standard therapeutic guidelines. The combikit of Fluconazole tablet, Azithromycin tablet and Ornidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. The above combikit is similar in nature and hence should be considered in the same category as already considered irrational by the DTAB. There is no convincing scientific/ clinical evidence/ justification for the combikit.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 760(E)	Combikit of Azithromycin dihydrate, secnidazole and fluconazole	Alembic Pharmaceuticals	Combikit of Azithromycin dihydrate IP eq. to Azithromycin anhydrous 1gm, secnidazole IP 1gm and fluconazole IP 150mg	Syndromic management of infection caused due to N. Gonorrorea, C. Trachomatis, Gardnerella vaginalis and anaerboes.	i. Same as Annexure-A ii. Not approved	Subcommittee noted that this FDC of Combipack of 1 tablet of Fluconazole 150mg ,1 film coated tablet of Azithromycin dihydrate eq. to Azithromycin 1gm & 2 film coated tabletof Secnidazole 1gm was approved by DCGI on 07.06.1999. The Subcommittee noted that: 1. The three diseases most frequently associated with vaginal discharge are Bacterial vaginosis, T. vaginalis, and candidiasis. (CDC STD Treatment guidelines). There is no role of azithromycin in the treatment any of these infections. 2. For the syndromic management of vaginal discharge, the National Guidelines on Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted Infections (July 2014) recommend: Tab. Secnidazole 2 gm orally, single dose (OR Tab. Tinidazole 500 mg orally, twice daily for 5 days OR Tab. Metronidazole 400 mg, twice daily for 7 days) Plus Tab Fluconazole 150mg orally single dose OR local Clotrimazole 500 mg vaginal pessary once. Azithromycin is not mentioned here. The National & International Standard Treatment guidelines for the management of PID, the anti-microbial combination recommended are Ceftriaxone + Doxycycline ± Metronidazole and for the vaginal discharge Tinidazole + Clindamycin + Fluconazole. Azithromycin is not mentioned as combination therapy in both of the above conditions. Azithromycin is mentioned for the use in Cervicitis/ Urethritis/ Mucopurulent Gonococcal in combination with Ceftriaxone. 3. The combination of the three drugs in the treatment of indications mentioned by the company is not recommended by standard therapeutic guidelines. The combikit of Fluconazole tablet, Azithromycin tablet and Ornidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. The above combikit is similar in nature and hence should be considered in the same category as already considered irrational by the DTAB. There is no convincing scientific/ clinical evidence/ justification for the combikit.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 760(E)	Combikit of Azithromycin dihydrate, secnidazole and fluconazole	Meridian Medicare	Combikit of 1 tablet of Azithromycin dihydrate 1000mg, 2 tablet of secnidazole 1000mg and 1 tablet of Fluconazole 150mg combipack	Syndromic treatment of vaginal discharge caused by trichomonal vaginitis, moniliasis, Chlamydia,gonorrhoea and bacterial vaginosis.	i.Not submitted. Ii.Not submitted	Subcommittee noted that this FDC of Combipack of 1 tablet of Fluconazole 150mg ,1 film coated tablet of Azithromycin dihydrate eq. to Azithromycin 1gm & 2 film coated tabletof Secnidazole 1gm was approved by DCGI on 07.06.1999. The Subcommittee noted that: 1. The three diseases most frequently associated with vaginal discharge are Bacterial vaginosis, T. vaginalis, and candidiasis. (CDC STD Treatment guidelines). There is no role of azithromycin in the treatment any of these infections. 2. For the syndromic management of vaginal discharge, the National Guidelines on Prevention, Management and Control of Reproductive Tract Infections and Sexually Transmitted Infections (July 2014) recommend: Tab. Secnidazole 2 gm orally, single dose (OR Tab. Tinidazole 500 mg orally, twice daily for 5 days OR Tab. Metronidazole 400 mg, twice daily for 7 days) Plus Tab Fluconazole 150mg orally single dose OR local Clotrimazole 500 mg vaginal pessary once. Azithromycin is not mentioned here. The National & International Standard Treatment guidelines for the management of PID, the anti-microbial combination recommended are Ceftriaxone + Doxycycline ± Metronidazole and for the vaginal discharge Tinidazole + Clindamycin + Fluconazole. Azithromycin is not mentioned as combination therapy in both of the above conditions. Azithromycin is mentioned for the use in Cervicitis/ Urethritis/ Mucopurulent Gonococcal in combination with Ceftriaxone. 3. The combination of the three drugs in the treatment of indications mentioned by the company is not recommended by standard therapeutic guidelines. The combikit of Fluconazole tablet, Azithromycin tablet and Ornidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. The above combikit is similar in nature and hence should be considered in the same category as already considered irrational by the DTAB. There is no convincing scientific/ clinical evidence/ justification for the combikit.
56	S.O. 760(E)	Combikit of Azithromycin dihydrate, secnidazole and fluconazole	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 761(E)	Levofloxacin + Ornidazole + Alpha Tocopherol Acetate	-	-	-	-	1. Indications of levofloxacin and ornidazole are different. Use of this FDC is inappropriate as one or the other ingredient would be unnecessary in a given condition. 2. Use may encourage emergence of antibiotic resistance against quinolones. 3. There is no medical condition which requires the co-administration of levofloxacin, ornidazole and alpha tocopherolacetate. The latter a vitamin E derivative has no role in treatment of infections. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines 6. Levofloxacin is in the WHO 'watchgroup antimicrobials' (has higher resistance potential and is to be used only for specific indications). Including it in an FDC will result in its indiscriminate use. There is no convincing scientific/ clinical evidence/ justification for the FDC.
57	S.O. 761(E)	Levofloxacin + Ornidazole + Alpha Tocopherol Acetate	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 762(E)	Nimorazole + Ofloxacin	Safetab	Each film coated tablet contains: Nimorazole 500mg + Ofloxacin Ip 200mg	For the treatment of mixed dental infection and diarrhea of mixed infection in adults	i. For the treatment of mixed dental infection and diarrhea of mixed infection in adults caused by susceptible gram-positive and gram-negative organisms along with anaerobes or protozoa ii NA	1. Indications of ofloxacin and nimorazole are different. Use of this FDC is inappropriate as one or the other ingredient would be unnecessary in a given condition. 2. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate, whereby increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC
58	S.O. 762(E)	Nimorazole + Ofloxacin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 763(E)	Azithromycin + ofloxacin	Aeon Formulations	Azithromycin Dihydrate IP eq. to Azithromycin (Anhydrous) 100mg+ ofloxacin IP 100mg uncoated tablet	Respiratory tract infections	Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Treatment of Respiratory tract infections and community acquired pneumonia. ii.Not submitted.	1. This combination is not as per standard therapeutic guidelines (National or International) for management of Respiratory infection & Community acquired pneumonia. 2. There is a mismatch in dosing schedule as Azithromycin has to be given once daily and Ofloxacin twice daily. 3. Both Azithromycin and Ofloxacin prolong QTc interval. 4. Fluoroquinolones including Ofloxacin are an integral part of MDR-TB therapy and should not be used in combination for any other indication. There is no convincing scientific/ clinical evidence/ justification for the FDC for any of the indications mentioned by the company.
	S.O. 763(E)	Azithromycin + ofloxacin	Alkem Laboratories Ltd.	Azithromycin Dihydrate IP eq. to Azithromycin (Anhydrous) 500mg+ ofloxacin IP 400mg uncoated tablet	Typhoid fever	i Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Acute bacterial sinusitis, acute bacterial otitis media, pharyngitis/ tonsilitis, lower respiratory tract infections, skin and soft tissue infections ii.Not submitted.	1. This combination is not as per standard therapeutic guidelines (National or International) for management of Respiratory infection & Community acquired pneumonia. 2. There is a mismatch in dosing schedule as Azithromycin has to be given once daily and Ofloxacin twice daily. 3. Both Azithromycin and Ofloxacin prolong QTc interval. 4. Fluoroquinolones including Ofloxacin are an integral part of MDR-TB therapy and should not be used in combination for any other indication. There is no convincing scientific/ clinical evidence/ justification for the FDC for any of the indications mentioned by the company.
59	S.O. 763(E)	Azithromycin + ofloxacin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 764(E)	Amoxycillin + Tinidazole	Theon Pharmaceuticals	Amoxycillin trihydrate IP eq. to Amoxycillin 500mg+ Tinidazole IP 300mg tablet	An anti-parasitic prescribed for trichomoniasis, giardiasis, bacterial vaginosis and amebiasis infection in different part of the body caused by bacteria. It is used to stop infection in case of tooth removal or other surgery.	i) Not submitted ii) Not submitted	1. Therapeutic claims as made by the appellant in the list of indications submitted for this FDC has no scientific basis. 2. The strengths of ingredients are subtherapeutic and FDC is not useful in practice considering the dose mentioned in treatment guidelines for *H.pylori* infection. 3. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 764(E)	Amoxycillin + Tinidazole	Dr. Reddy's Laboratories	Amoxycillin Trihydrate IP eq. to Amoxicillin 500mg+ Tinidazole IP 300mg film coated tablets	For eradication of H. Pylori in patients with peptic ulcer disease as adjuvant therapy with PPIs	i) same as Annexure A ii) Not approved	1. Therapeutic claims as made by the appellant in the list of indications submitted for this FDC has no scientific basis. 2. The strengths of ingredients are subtherapeutic and FDC is not useful in practice considering the dose mentioned in treatment guidelines for *H.pylori* infection. 3. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
60	S.O. 764(E)	Amoxycillin + Tinidazole	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation::** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	I. Indicaiton as per package insert II. If marketing any where	
	S.O. 765(E)	Doxycyclin + Serratiopeptidase	-	-	-	-	1. Pharmacodynamically irrelevant. There is no sound clinical evidence for concurrent use of Doxycycline & Serratiopeptidase. 2. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 3. This combination is not as per standard therapeutic guidelines
61	S.O. 765(E)	Doxycyclin + Serratiopeptidase	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 766(E)	Cefixime + levofloxacin	Akums Drugs	Cefixime IP (as Trihydrate) eq. To Anhydrous Cefixime 400mg +levofloxacin Hemihydrate IP eq. To Levofloxacin 500mg film coated tablet	Infection caused by organisms susceptible to cefixime and l or levofloxacin:- moderate to severe respiratory infections like community acquired pneumonia, acute exacerbation of chronic bronchitis, etc. Enteric fever, UTI.	i. Same as Annexure-A ii. Not Submitted	The "10 expert committee report" stated that: "IDSA/ATS guidelines do not mention treatment with this FDC in outpatient management. Further, firm also did not present any data on safety and efficacy of FDC and the FDC is not approved anywhere in the world. It was observed that misuse potential of this FDC is very high which will cause anti- microbial drug resistance." Subcommittee agreed with the above comments. 1. This combination is not as per standard therapeutic guidelines for the treatment of RTI, UTI. 2. Monotherapy with Fluoroquinolones or cephalosporins is preferred in enteric fever. 3. Fluoroquinolones should not be used for empirical treatment for outpatient management of CAP unless Tuberculosis is ruled out (NCCP). 4. The Subcommittee notes that levofloxacin is an integral part of MDR-TB therapy and should not be used in combination for any other indication. There is no convincing scientific/ clinical evidence/ justification for the FDC.
62	S.O. 766(E)	Cefixime + levofloxacin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 767(E)	Ofloxacin + Metronidazole + Zinc Acetate	-	-	-	-	1. Pharmacokinetic mismatch: Ofloxacin is given two times a day whereas Metronidazole is given three times a day. 2. Indications of ofloxacin and metronidazole are different. Use of this FDC is inappropriate as one or the other ingredient would be unnecessary in a given condition. 3. There is no medical condition which requires the co-administration of ofloxacin, metronidazole and zinc acetate. Zinc acetate has no role in treatment of infections. This combination is not as per standard therapeutic guidelines. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects and development of antimicrobial resistance. There is no convincing scientific/ clinical evidence/ justification for the FDC.
63	S.O. 767(E)	Ofloxacin + Metronidazole + Zinc Acetate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 768(E)	Diphenoxylate + Atropine + Furazolidone	-	-	-	-	1. Use of antispasmodic and anti-infective agent in an FDC can not be justified because the former is meant for symptomatic relief and is given as and when required (SOS) while the latter is for treating an infection that requires repeated dosing (furazolidine is to be given four times a day) for few days. 2. Furazolidone is not a drug of choice for infective diarrhoea and better alternatives are available. Its use is associated with side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
64	S.O. 768(E)	Diphenoxylate + Atropine + Furazolidone	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 769(E)	Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets	Systopic Laboratories	Combikit of Fluconazole Tablet 150mg, Azithromycin Tablet 1gm and Ornidazole Tablets 750mg	As an anti bacterial in gynaecological conditions.	i. AF-KIT is indicated for the syndromic management of vaginal discharge of various etiologies like candidiasis, bacterial vaginosis, Trichomoniasis, chlamydial infections or due to mixed infections caused by these organisms. ii.Not submitted	DTAB Subcommittee noted that the combikit of Fluconazole tablet, Azithromycin tablet and Ornidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. Hence, the Subcommittee did not review as the report of DTAB for 294 category is already accepted by the Hon'ble Supreme court of India. At the time of hearing company representative was informed the court order as above.
65	S.O. 769(E)	Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets	DTAB sub-committee noted that the combikit of Fluconazole tablet, Azithromycin tablet and Ornidazole tablet was already considered as irrational by DTAB under the 294 FDCs category. Hence, the sub-committee did not review as the report of DTAB for 294 category is already accepted by the Hon'ble Supreme court of India.				

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 770(E)	Ciprofloxacin + Phenazopyridine	Tidal Laboratories	Ciprofloxacin USP 250mg+ Phenazopyridine IP 200mg tablet	Urinary tract infections At the time of hearing, the company requested for the revision of indications as under: Short course two day therapy in uncomplicated UTI (cystitis, urethritis).	Not Submitted	Already discussed by "10 expert Committee" on 11.06.2014 and they opined as under- "Ciprofloxacin is an antibiotic and phenazopyridine is urinary analgesic for symptomatic relief. Normally ciprofloxacin is used for 5 to 7 days but phenazopyridine is not recommended for more than 2 days due to its serious side effects. Hence, this combination is not rational and the committee did not recommend for approval." The Subcommittee concurred with the "10 expert committee" opinion . The Subcommittee noted that : 1.The combination is Pharmacokinetically a mismatch as phenazopyridine is given thrice daily, whereas oral ciprofloxacin is usually given twice daily. 2.There is also a mismatch in the duration for which these two drugs are required to be given. Phenazopyridine is intended for short-term use (usually 2 days), as this is potentially associated with complications such as renal or liver dysfunction and is not required to be given for symptomatic treatment as antimicrobial agent starts working. However, Ciprofloxacin therapy is required to be given for 3-7 days. 3. This combination is not as per standard therapeutic guidelines 4. At the time of hearing company informed that the product is marketed in Mexico. Sulfatrimethoprim + Phenazopyridine was marketed in USA but discontinued. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 770(E)	Ciprofloxacin + Phenazopyridine	Aeon Formulations	Ciprofloxacin Hydrochloride IP eq. to Ciprofloxacin 250mg+ Phenazopyridine Hydrochloride USP 200mg film coated tablet	Painful micturition to Urinary Tract Infections	i.Indication is same as Annexuere-A. ii. Not submitted.	Already discussed by "10 expert Committee" on 11.06.2014 and they opined as under- "Ciprofloxacin is an antibiotic and phenazopyridine is urinary analgesic for symptomatic relief. Normally ciprofloxacin is used for 5 to 7 days but phenazopyridine is not recommended for more than 2 days due to its serious side effects. Hence, this combination is not rational and the committee did not recommend for approval." The Subcommittee concurred with the "10 expert committee" opinion . The Subcommittee noted that : 1.The combination is Pharmacokinetically a mismatch as phenazopyridine is given thrice daily, whereas oral ciprofloxacin is usually given twice daily. 2.There is also a mismatch in the duration for which these two drugs are required to be given.Phenazopyridine is intended for short-term use (usually 2 days), as this is potentially associated with complications such as renal or liver dysfunction and is not required to be given for symptomatic treatment as antimicrobial agent starts working. However, Ciprofloxacin therapy is required to be given for 3-7 days. 3. This combination is not as per standard therapeutic guidelines 4. At the time of hearing company informed that the product is marketed in Mexico. Sulfatrimethoprim + Phenazopyridine was marketed in USA but discontinued. There is no convincing scientific/ clinical evidence/ justification for the FDC.
66	S.O. 770(E)	Ciprofloxacin + Phenazopyridine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **1. The FDC may involve unnecessary exposure to two drugs (for duration & frequency not required) increasing the risk of side effects to human beings.** **2. There is no therapeutic justification for the ingredients contained in this FDC as the duration & frequency of treatment for the two drugs is different.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**					

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	I. Indication as per package insert ii. If marketing any where	
	S.O.771(E)	Amoxycillin + Dicloxacillin + Serratiopeptidase	-	-	-	-	1. Dicloxacillin is indicated for the treatment of infections caused by penicillinase producing organisms that are resistant to Amoxicillin. Hence, the combination of Amoxycillin + Dicloxacillin is irrational. 2. Amoxicillin is to be given three times a day whereas Dicloxacillin is to be given four times a day making the combination Pharmacokinetically incompatible. 3. The FDC may involve unnecessary exposure to two anti-microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 4. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. 5. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
67	S.O.771(E)	Amoxycillin + Dicloxacillin + Serratiopeptidase	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 772(E)	Azithromycin + Cefpodoxime	Lifestar	Cefpodoxime Proxetil IP eq. To Anhydrous Cefpodoxime 200mg+ Azithromycin IP as Dihydrate eq. To Anhydrous Azithromycin 250mg film coated tablet	Treatment of lower respiratory tract infections. At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae with co-morbitities.	i. Same as Annexure-A ii. Not approved	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti-microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 772(E)	Azithromycin + Cefpodoxime	Glenmark	Cefpodoxime Proxetil IP eq. To Cefpodoxime 200mg/200mg+ Azithromycin IP as Dihydrate eq. To Anhydrous Azithromycin 250mg/500mg tablet	treatment of uncomplicated enteric fever that has been inadequately controlled by individual monocomponents or treatment of uncomplicated MDR enteric fever. At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae with co-morbitities.	i. Same as Annexure-A ii. Not approved	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concurred with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam anti-microbial agent for the treatment of RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti-microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 772(E)	Azithromycin + Cefpodoxime	Macleods	Azithromycin 250mg+ Cefpodoxime 200mg tablets	Treatment of respiratory tract infections At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae with co-morbitities.	i. Same as Annexure-A ii. Not approved	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam antimicrobial agent for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 772(E)	Azithromycin + Cefpodoxime	Theon Pharmaceuticals	Azithromycin dihydrate IP eq. to Azithromycin anhydrous 250mg+ Cefpodoxime proxetil IP eq. to Cefpodoxime 200mg film coated tablets	Treatment of sinusitis,bronchitis and pneumonia At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae with co-morbitities.	i. Not Submitted ii. Not Approved	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam antimicrobial agent for the treatment of RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti-microbials where one is adequate increasing the risk of developing anti-microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 772(E)	Azithromycin + Cefpodoxime	Hetero Healthcare	Azithromycin dihydrate IP eq. to Azithromycin 250mg+ Cefpodoxime proxetil IP eq. to Cefpodoxime 200mg film coated tablets	Treatment of respiratory tract infections (Both upper and lower RTIs), multi drug resistant typhoid fever At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae.	i. Not Submitted ii. Not Approved	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concurred with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 772(E)	Azithromycin + Cefpodoxime	Sun Pharma Industries	Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg+ Azithromycin Dihydrate IP eq. to Azithromycin 250mg film coated tablets	Treatment of community-acquired pneumonia. At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae with co-morbitities.	i. Same as Annexure-A ii. Not approved	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 772(E)	Azithromycin + Cefpodoxime	Mascot Healthcare	Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg+ Azithromycin IP 250mg film coated tablets	Skin and skin structure infections, infections of the throat, pharyngitis and tonsillitis, community acquired pneumonia anorectal infections in woman. At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae with co-morbitities.	i. Indications mentioned in package insert are for individual drugs and not for FDC. ii Firm claimed that FDC is marketed and approved in India. However no proofis submitted in this regard.	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 772(E)	Azithromycin + Cefpodoxime	Acon Formulations	Azithromycin 100mg/ 200mg/ 200mg+ Cefpodoxime 125mg/ 250mg/ 500mg uncaoted dispersible tablet	Treatment of Community acquired Pneumonia. At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae with co-morbitities.	i. Same as Annexure-A ii. Not approved	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 772(E)	Azithromycin + Cefpodoxime	relax pharmaceuticals	Azithromycin 100mg/200mg/200mg+ Cefpodoxime 125mg/250mg/500mg uncaoted dispersible tablet	Used in treatment respiratory tract infections. At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae with co-morbitities.	Used in treatment Lower respiratory tract infections.	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 772(E)	Azithromycin + Cefpodoxime	Corona Remedies	Azithromycin Dihydrate IP eq. to Azithromycin Abhydrous 250mg+ Cefpodoxime proxeil IP Eq. to Cefpodoxime 200mg film coated tablets	For treatment, control, prevention and improvement of following diseases, conditions and symptoms; Skin and skin structures Infection, Gonorrhea, Acute Maxillary Sinusitis, bacterial infections, Chronic bronchitis exacerbations, Urinary tract infections, Acute otitis media, Pharyngitis and tonsilitis, community acquired pneumonia. At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae with co-morbitities.	i.Not submitted. Ii.Not submitted	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

ame

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 772(E)	Azithromycin + Cefpodoxime	Wings Phamaceuticals Ltd.	Azithromycin Dihydrate IP eq. to Azithromycin Abhydrous 250mg+ Cefpodoxime proxeil IP Eq. to Cefpodoxime 200mg film coated tablets	Antibiotics At the time of hearing, the company requested for the revision of indications as under: Community acquired pneumoniae.	i.Indications mentioned in package insert are different from that mntioned in Annexure A. Indications mentioned in package inset are as under: Upper and lower respiratory tract infections, Otitis media, tonsilitis and pharyngitis, pneumonia Ii.Not submitted	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 772(E)	Azithromycin + Cefpodoxime	Akums Drugs	Azithromycin Dihydrate IP eq. to Azithromycin Abhydrous 250mg+ Cefpodoxime proxeil IP Eq. to Cefpodoxime 200mg film coated tablets	used in the treatment of soft tissue infection, lower and upper respiratory tract infections and other infections	i.Same as Annexure-A. ii.Not submitted	This FDC was discussed by "10 expert committee" and the comments are as under: "Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. Therefore the proposed FDC is not recommended for approval." The Subcommittee concured with the comments of "10 expert committee" as above. Subcommittee noted that: 1. Cefpodoxime is not listed under preferred beta lactam for RTI (NCCP guidelines), but it is listed under alternative (ATS guidelines). 2. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. There is no convincing scientific/ clinical evidence/ justification for the FDC.
68	S.O. 772(E)	Azithromycin + Cefpodoxime	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 773(E)	Lignocaine+ Clotrimazole+ Ofloxacin+ Beclomethasone	Glenmark	Lidocaine BP 1.73%w/v+Clotrimazole IP 1%w/v+Ofloxacin IP 0.30%w/v+Beclomethasone Dipropionate IP 0.025%w/v ear drops	Treatment of acute otitic externa (AOE) with intact tympanic membrane	i. Indication same as Annexure A. ii. Not approved	1. Pharmacodynamically inappropriate: Each ingredient of FDC has different therapeutic indications. There is no study found supporting the combined use of an antibacterial (Ofloxacin) with an antifungal (Clotrimazole) ingredient. 2. Combining antibacterial, antifungal, steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & Clinical Trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 773(E)	Lignocaine+ Clotrimazole+ Ofloxacin+ Beclomethasone	Centaur	Lignocaine HCl IP 2%w/v+Clotrimazole IP 1%w/v+Ofloxacin IP 0.3%w/v+Beclomethasone Dipropionate IP 0.025%w/v ear drops	Chronic Suppurative otitis media, Acute otitis Media, Otitis Externa. At the time of hearing, the appellant informed that they wished to delete *otitis media* from the list of indications.	i. Indication same as Annexure A. ii. Not approved	1. Pharmacodynamically inappropriate: Each ingredient of FDC has different therapeutic indications. There is no study found supporting the combined use of an antibacterial (Ofloxacin) with an antifungal (Clotrimazole) ingredient. 2. Combining antibacterial, antifungal, steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & Clinical Trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.

me

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 773(E)	Lignocaine+ Clotrimazole+ Ofloxacin+ Beclomethasone	Puro Pharma	Lignocaine HCl IP 2%w/v+Clotrimazole IP 1%w/v+Ofloxacin IP 0.3%w/v+Beclomethasone Dipropionate IP 0.025%w/v ear drops	Chronic Suppurative otitis media, Acute otitis Media, Otitis Externa.	i. Indication same as Annexure A. ii. Not approved	1. Pharmacodynamically inappropriate: Each ingredient of FDC has different therapeutic indications. There is no study found supporting the combined use of an antibacterial (Ofloxacin) with an antifungal (Clotrimazole) ingredient. 2. Combining antibacterial, antifungal, steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & Clinical Trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 773(E)	Lignocaine+ Clotrimazole+ Ofloxacin+ Beclomethasone	Jenburkt Pharmaceuticals	Lignocaine HCl IP 2.0%w/v+Clotrimazole IP 1.0%w/v+Ofloxacin IP 0.3%w/v+Beclomethasone Dipropionate IP 0.025%w/v ear drops	Otitis Externa	i.Not submitted. ii. Not approved	1. Pharmacodynamically inappropriate: Each ingredient of FDC has different therapeutic indications. There is no study found supporting the combined use of an antibacterial (Ofloxacin) with an antifungal (Clotrimazole) ingredient. 2. Combining antibacterial, antifungal, steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & Clinical Trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
69	S.O. 773(E)	Lignocaine+ Clotrimazole+ Ofloxacin+ Beclomethasone	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 774(E)	Cefuroxime + Linezolid	Macleods	Cefuroxime Axetil IP eq. To Cefuroxime 500mg+ Linezolid IP 600mg film coated tablet	it is indicated for the treatment of respiratory tract infection and skin and soft tissue infections.	i. Same as Annexure-A ii. Not Submitted	1. Linezolid has been categorized as one of the RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). The use of linezolid in India should be reserved because of its potential use in extensively drug-resistant TB (NCCP). Hence, it is not appropriate for Linezolid to be formulated as an FDC. 2. Cefuroxime needs dose adjustment in renally impaired patents (CrCl<20 mL/min) whereas linezolid does not, implying that the combination is not appropriate for selected patients with renal impairment. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. 4. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 774(E)	Cefuroxime + Linezolid	Micro	Cafuroxime Axetil IP eq.to Cefuroxime 500mg + Linezolid IP 600mg film coated tablet	it is indicated for the treatment of respiratory tract infections.	i. Same as Annexure-A ii. NotSubmitted	1. Linezolid has been categorized as one of the RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). The use of linezolid in India should be reserved because of its potential use in extensively drug-resistant TB (NCCP). Hence, it is not appropriate for Linezolid to be formulated as an FDC. 2. Cefuroxime needs dose adjustment in renally impaired patents (CrCl<20 mL/min) whereas linezolid does not, implying that the combination is not appropriate for selected patients with renal impairment. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. 4. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 774(E)	Cefuroxime + Linezolid	Akums Drugs	Cefuroxime Axetil IP eq. to Cefuroxime 500mg+ Linezolid IP 600mg film coated tablet	It is indicated for the treatment of: community acquired & nosocomial pneumonia, skin and skin structure infections, respiratory tract infection, urinary tract infection and gonococcal urethritis	i. Same as Annexure-A ii. NotSubmitted	1. Linezolid has been categorized as one of the RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). The use of linezolid in India should be reserved because of its potential use in extensively drug-resistant TB (NCCP). Hence, it is not appropriate for Linezolid to be formulated as an FDC. 2. Cefuroxime needs dose adjustment in renally impaired patents (CrCl<20 mL/min) whereas linezolid does not, implying that the combination is not appropriate for selected patients with renal impairment. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. 4. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 774(E)	Cefuroxime + Linezolid	Koye Pharmaceuticals	Cefuroxime Axetil IP eq. to Cefuroxime 500mg+ Linezolid IP 600mg film coated tablet	Nosocomial pneumonia caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates) or Streptococcus pneumonia. Community-acquired pneumonia caused by Streptococcus pneumoniae or Staphylococcus aureus Uncomplicated and complicated skin and skin structure infections, including diabetic foot infections, caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus pyogenes, or Streptococcus agalactiae. At the time of hearing, the company requested for the revision of indications as under: Lower respiratory tract infection with MRSA.	i. Same as Annexure-A ii. NotSubmitted	1. Linezolid has been categorized as one of the RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). The use of linezolid in India should be reserved because of its potential use in extensively drug-resistant TB (NCCP). Hence, it is not appropriate for Linezolid to be formulated as an FDC. 2. Cefuroxime needs dose adjustment in renally impaired patents (CrCl<20 mL/min) whereas linezolid does not, implying that the combination is not appropriate for selected patients with renal impairment. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. 4. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 774(E)	Cefuroxime + Linezolid	Mascot Healthcare	Cefuroxime Axetil IP eq. to Cefuroxime 500mg+ Linezolid IP 600mg film coated tablet	Pharyngitis, Tonsillitis sinusitis, acute bacterial Otitis Media, Pneumonia, chronic Bronchitis, Skin and soft tissue infection.	i. Not Submitted ii. Not Approved	1. Linezolid has been categorized as one of the RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). The use of linezolid in India should be reserved because of its potential use in extensively drug-resistant TB (NCCP). Hence, it is not appropriate for Linezolid to be formulated as an FDC. 2. Cefuroxime needs dose adjustment in renally impaired patents (CrCl<20 mL/min) whereas linezolid does not, implying that the combination is not appropriate for selected patients with renal impairment. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. 4. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 774(E)	Cefuroxime + Linezolid	Zaneka Healthcare	Cefuroxime Anextil IP eq. to Cefuroxime 500mg+ Linezolid IP 600mg film coated tablet	U.R.T.I, Otitis, Sinusitis, tonsillitis, Pharyngitis, urinary tract infection, urethritis, cystis, ENT infection and Gonorrhea	i. Not Submitted ii. Not Submitted	1. Linezolid has been categorized as one of the RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). The use of linezolid in India should be reserved because of its potential use in extensively drug-resistant TB (NCCP). Hence, it is not appropriate for Linezolid to be formulated as an FDC. 2. Cefuroxime needs dose adjustment in renally impaired patents (CrCl<20 mL/min) whereas linezolid does not, implying that the combination is not appropriate for selected patients with renal impairment. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. 4. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 774(E)	Cefuroxime + Linezolid	Corona Remedies	Cefuroxime Axetil IP eq. to Cefuroxime 500mg+ Linezolid IP 600mg film coated tablet	For treatment, control, prevention and improvement of following diseases, conditions and symptoms; Acute Pharyngitis and tonsillitis, Acute bacterial sinusitis, Acute bacterial otitis media Acute exacerbations chronic bronchitis, cystitis, pyelonephritis, lyme disease, Noscomical pneumonia,community acquired pneumonia, un/complicated skin and tissue infections.	i.Not submitted. Ii.Not submitted	1. Linezolid has been categorized as one of the RESERVE group antibiotics by WHO whose use should be tailored to highly specific patients and settings, when all alternatives have failed (eg. Serious, life-threatening infections due to multi-drug resistant bacteria). The use of linezolid in India should be reserved because of its potential use in extensively drug-resistant TB (NCCP). Hence, it is not appropriate for Linezolid to be formulated as an FDC. 2. Cefuroxime needs dose adjustment in renally impaired patents (CrCl<20 mL/min) whereas linezolid does not, implying that the combination is not appropriate for selected patients with renal impairment. 3. This combination is not as per standard therapeutic guidelines for indications mentioned by the company. 4. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
70	S.O. 774(E)	Cefuroxime + Linezolid	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 775(E)	Ofloxacin + Ornidazole + Zinc bisglycinate	-	-	-	-	1. Indications of ofloxacin and Ornidazole are different. Use of this FDC is inappropriate as one or the other ingredient would be unnecessary in a given condition. Diarrhoea due to mixed bacterial and parasitic infections is rare. 2. There is no medical condition which requires the co-administration of ofloxacin, ornidazole and zinc bisglycinate. Zinc bisglycinate has no role in treatment of infections. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance to Ofloxacon and also increasing the risk of side effects to human beings. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
71	S.O. 775(E)	Ofloxacin + Ornidazole + Zinc bisglycinate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 776(E)	Metronidazole + Norfloxacin	J. B. Chemicals	Metronidazole Benzoate IP eq. To Metronidazole 100mg+ Norfloxacin IP 100mg per 5ml suspension	For the treatment of diarrhoea of mixed infection	i) same as Annexure A ii) Not approved	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection is uncommon and epidemiological data could not be provided by the appellant. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. This combination is not mentioned in standard treatment guidelines. 5. Safety concern for use of Norfloxacin in paediatric patients. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 776(E)	Metronidazole + Norfloxacin	Sun	Metronidazole IP 500mg+ Norfloxacin IP 400mg film coated tablet	For the treatment of diarrhoea and dysentery of amoebic, bacterial or mixed origins	i) same as Annexure A ii) Not approved	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection is uncommon and epidemiological data could not be provided by the appellant. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. This combination is not mentioned in standard treatment guidelines. 5. Safety concern for use of Norfloxacin in paediatric patients. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 776(E)	Metronidazole + Norfloxacin	Sun	Metronidazole Benzoate IP eq. To Metronidazole 100mg+ Norfloxacin IP 100mg per 5ml suspension	For the treatment of diarrhoea and dysentery of amoebic, bacterial or mixed origins	i) same as Annexure A ii) Not approved	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection is uncommon and epidemiological data could not be provided by the appellant. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. This combination is not mentioned in standard treatment guidelines. 5. Safety concern for use of Norfloxacin in paediatric patients. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 776(E)	Metronidazole + Norfloxacin	Pharose Remedies	Norfloxacin IP 400mg+ Metronidazole IP 500mg film coated tablet	For the treatment of diarrhoea caused by E. Coli, Salmonella and Shigella	i) same as Annexure A ii) Not provided	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection is uncommon and epidemiological data could not be provided by the appellant. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. This combination is not mentioned in standard treatment guidelines. 5. Safety concern for use of Norfloxacin in paediatric patients. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 776(E)	Metronidazole + Norfloxacin	Lark Laboratories	Metronidazole IP 200mg+ Norfloxacin IP 200mg tablets	mixed abdominal infection	i) Not submitted ii) Not submitted	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection is uncommon and epidemiological data could not be provided by the appellant. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. This combination is not mentioned in standard treatment guidelines. 5. Safety concern for use of Norfloxacin in paediatric patients. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 776(E)	Metronidazole + Norfloxacin	Lark Laboratories	Metronidazole IP 100mg+ Norfloxacin IP 100mg tablets	mixed abdominal infection	i) same as annexure A ii) Not submited	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection is uncommon and epidemiological data could not be provided by the appellant. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. This combination is not mentioned in standard treatment guidelines. 5. Safety concern for use of Norfloxacin in paediatric patients. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 776(E)	Metronidazole + Norfloxacin	Celsius Healthcare	Metronidazole IP 200mg+ Norfloxacin IP 100mg per 5ml suspension	for treatment of diarrhea	i) Not submitted ii) Not submitted	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection is uncommon and epidemiological data could not be provided by the appellant. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. This combination is not mentioned in standard treatment guidelines. 5. Safety concern for use of Norfloxacin in paediatric patients. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 776(E)	Metronidazole + Norfloxacin	Combitic Global	Metronidazole IP 400mg+ Norfloxacin IP 400mg film coated tablets	Antibiotic	i) Not submitted ii) Not submitted	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection is uncommon and epidemiological data could not be provided by the appellant. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. This combination is not mentioned in standard treatment guidelines. 5. Safety concern for use of Norfloxacin in paediatric patients. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 776(E)	Metronidazole + Norfloxacin	Combitic Global	Metronidazole IP 400mg+ Norfloxacin IP 400mg film coated tablets	Antibiotic	i) Not submitted ii) Not submitted	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection is uncommon and epidemiological data could not be provided by the appellant. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. This combination is not mentioned in standard treatment guidelines. 5. Safety concern for use of Norfloxacin in paediatric patients. There is no sound scientific/ clinical evidence/ justification for the FDC.
72	S.O. 776(E)	Metronidazole + Norfloxacin	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 777(E)	Amoxicillin+ Bromhexine	Coral Laboratories/ DWD Pharmaceutica ls	Each capsule contains: Amoxicillin 250/500+ Bromhexine 8/8mg & Each Dispersible tablet contains: Amoxicillin 250mg+ Bromhexine 8mg	AECB, COPD, Chronic Bronchitis, Bronchial Asthma	i. Package insert not submitted ii. NA	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee futher noted that: 1. There is no clinical evidence of benefit of the combination of Amoxicillin and Bromhexine. 2.The combination is not as per Standard treatment Guidelines. 3. The combination is not indicated in patients with bronchial asthma. Bromhexine is required for liquefaction of mucus in patients with COPD but additional anti-microbial agent is required only in presence of infection for a shorter period of time. 4. Combining Amoxicillin with a non-antimicrobial agent like Bromhexine may lead to inadvertent use/overuse of Amoxicillin and emergence of resistance. There is no sound scientific/ clinical evidence/ justification for the FDC.
73	S.O. 777(E)	Amoxicillin+ Bromhexine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. There is no therapeutic value. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

me

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 778(E)	Ciprofloxacin +Fluticasone +Clotrimazole +Neomycin	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining two antibacterials (Ciprofloxacin, Neomycin) , antifungal (Clotrimazole), steroid (Fluticasone) in the present FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of steroid. 3. No study is found supporting the combined use of ingredients in this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
74	S.O. 778(E)	Ciprofloxacin +Fluticasone +Clotrimazole +Neomycin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 779(E)	Metronidazole + Tetracycline	-	-	-	-	1. The combination of Metronidazole and Tetracycline is not justified in any clinical condition and is irrational. 2. This combination is not as per standard therapeutic guidelines. 3. The FDC may involve unnecessary exposure to two anti microbials where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no convincing scientific/ clinical evidence/ justification for the FDC.
75	S.O. 779(E)	Metronidazole + Tetracycline	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 780(E)	Cephalexin + Neomycin + Prednisolone	-	-	-	-	1.Pharmacodynamically irrelevant- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antibiotics (Neomycin and Cephalexin) & steroid (Prednisolone) in this FDC. The FDC is likely to cause emergence of resistance and adverse effects. 2. No study to support the combined use of ingredients in this FDC. 3.This FDC has no defined therapeutic area and patient population. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
78	S.O. 780(E)	Cephalexin + Neomycin + Prednisolone	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 781(E)	Azithromycin+ Ambroxol	FDC	Azithromycin IP as dehydrate eq. To Anhydrous Azithromycin 500mg+ Ambroxol HCl IP 75mg (SR) film coated tablet	For RTI caused by susceptible organisms in adults	i) Indication same as Annexure-A ii) Not submitted	The Subcommittee noted that FDC of Azithromycin 500mg+ Ambroxol S.R (75mg) Tablet indicated for RTI caused by susceptible organisms in adults was approved by CDSCO on 05-07-2007. The Subcommittee further noted that: 1. There is no sufficient clinical evidence of benefit of the combination of Azithromycin and Ambroxol. 2. Combining Azithromycin with a non- antimicrobial agent may lead to overuse of Azithromycin and emergence of resistance. 3. There is pharmacokinetic incompatibility: The dosing schedule of Azithromycin is once a day whereas Ambroxol is thrice a day. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 781(E)	Azithromycin+ Ambroxol	Accent	Azithromycin IP as dehydrate eq. To Anhydrous Azithromycin 500mg+ Ambroxol HCl IP 60mg (SR) uncoated bilayered tablet	For RTI caused by susceptible organisms in adults	i)Indication not mentioned in the package insert ii) Not submitted	The Subcommittee noted that FDC of Azithromycin 500mg+ Ambroxol S.R (75mg) Tablet indicated for RTI caused by susceptible organisms in adults was approved by CDSCO on 05-07-2007. The Subcommittee further noted that: 1. There is no sufficient clinical evidence of benefit of the combination of Azithromycin and Ambroxol. 2. Combining Azithromycin with a non- antimicrobial agent may lead to overuse of Azithromycin and emergence of resistance. 3. There is pharmacokinetic incompatibility: The dosing schedule of Azithromycin is once a day whereas Ambroxol is thrice a day. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 781(E)	Azithromycin+ Ambroxol	Accent Pharma	Azithromycin 250mg+ Ambroxol 60mg tablets	For RTI caused by susceptible organisms in adults.	i) Indication same as Annexure-A ii) Not submitted	The Subcommittee noted that FDC of Azithromycin 500mg+ Ambroxol S.R (75mg) Tablet indicated for RTI caused by susceptible organisms in adults was approved by CDSCO on 05-07-2007. The Subcommittee further noted that: 1. There is no sufficient clinical evidence of benefit of the combination of Azithromycin and Ambroxol. 2. Combining Azithromycin with a non- antimicrobial agent may lead to overuse of Azithromycin and emergence of resistance. 3. There is pharmacokinetic incompatibility: The dosing schedule of Azithromycin is once a day whereas Ambroxol is thrice a day. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 781(E)	Azithromycin+ Ambroxol	Accent Pharma	Azithromycin 500mg+ Ambroxol HCl 60mg tablets	For RTI caused by susceptible organisms in adults	i) Indication same as Annexure-A ii) Not submitted	The Subcommittee noted that FDC of Azithromycin 500mg+ Ambroxol S.R (75mg) Tablet indicated for RTI caused by susceptible organisms in adults was approved by CDSCO on 05-07-2007. The Subcommittee further noted that: 1. There is no sufficient clinical evidence of benefit of the combination of Azithromycin and Ambroxol. 2. Combining Azithromycin with a non- antimicrobial agent may lead to overuse of Azithromycin and emergence of resistance. 3. There is pharmacokinetic incompatibility: The dosing schedule of Azithromycin is once a day whereas Ambroxol is thrice a day. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 781(E)	Azithromycin+ Ambroxol	Accent Pharma	Azithromycin 250mg+ Ambroxol HCl 60mg(SR) tablets	For RTI caused by susceptible organisms in adults.	i)Indication not mentioned in the package insert ii) Not submitted	The Subcommittee noted that FDC of Azithromycin 500mg+ Ambroxol S.R (75mg) Tablet indicated for RTI caused by susceptible organisms in adults was approved by CDSCO on 05-07-2007. The Subcommittee further noted that: 1. There is no sufficient clinical evidence of benefit of the combination of Azithromycin and Ambroxol. 2. Combining Azithromycin with a non- antimicrobial agent may lead to overuse of Azithromycin and emergence of resistance. 3. There is pharmacokinetic incompatibility: The dosing schedule of Azithromycin is once a day whereas Ambroxol is thrice a day. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 781(E)	Azithromycin+ Ambroxol	Akums Drugs	Azithromycin USP 500mg+ Ambroxol HCl BP 75mg SR film coated bilayered tablets	RTI caused by susceptible organisms in adults. All forms of tracheobronchitis emphysema with bronchitis pneumoconiosis chronic inflammatory pulmonary conditions, community-acquired pneumonia.	i) Indication same as Annexure-A ii) Not Approved	The Subcommittee noted that FDC of Azithromycin 500mg+ Ambroxol S.R (75mg) Tablet indicated for RTI caused by susceptible organisms in adults was approved by CDSCO on 05-07-2007. The Subcommittee further noted that: 1. There is no sufficient clinical evidence of benefit of the combination of Azithromycin and Ambroxol. 2. Combining Azithromycin with a non- antimicrobial agent may lead to overuse of Azithromycin and emergence of resistance. 3. There is pharmacokinetic incompatibility: The dosing schedule of Azithromycin is once a day whereas Ambroxol is thrice a day. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 781(E)	Azithromycin+ Ambroxol	Alembic Ltd.	Azithromycin IP (as dehydrate) eq. to Azithromycin Anhydrous 500mg+ Ambroxol Hydrochloride IP 75mg (as sustained release) film coated bilayered tablet	CAP (Mild), Pharyngitis/Tonsilitis, Acute Bacterial sinusitis	i) same as Annexure A ii) Not submitted	The Subcommittee noted that FDC of Azithromycin 500mg+ Ambroxol S.R (75mg) Tablet indicated for RTI caused by susceptible organisms in adults was approved by CDSCO on 05-07-2007. The Subcommittee further noted that: 1. There is no sufficient clinical evidence of benefit of the combination of Azithromycin and Ambroxol. 2. Combining Azithromycin with a non- antimicrobial agent may lead to overuse of Azithromycin and emergence of resistance. 3. There is pharmacokinetic incompatibility: The dosing schedule of Azithromycin is once a day whereas Ambroxol is thrice a day. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 781(E)	Azithromycin+ Ambroxol	Alembic Ltd.	Azithromycin IP (as dehydrate) eq. to Azithromycin Anhydrous 250mg+ Ambroxol Hydrochloride IP 75mg (as sustained release) film coated bilayered tablet	CAP (Mild), Pharyngitis/Tonsilitis, Acute Bacterial sinusitis	i) same as Annexure A ii) Not submitted	The Subcommittee noted that FDC of Azithromycin 500mg+ Ambroxol S.R (75mg) Tablet indicated for RTI caused by susceptible organisms in adults was approved by CDSCO on 05-07-2007. The Subcommittee further noted that: 1. There is no sufficient clinical evidence of benefit of the combination of Azithromycin and Ambroxol. 2. Combining Azithromycin with a non- antimicrobial agent may lead to overuse of Azithromycin and emergence of resistance. 3. There is pharmacokinetic incompatibility: The dosing schedule of Azithromycin is once a day whereas Ambroxol is thrice a day. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
77	S.O. 781(E)	Azithromycin+ Ambroxol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 782(E)	Cilnidipine + metroprolol succinate + metroprolol tartrate	Mascot	Metoprolol Succinate eq. To Metoprolol Tartrate 50mg + Cilnidipine 10mg film coated tablets	Hypertention with or without Cardiac failure	i. Indication for Metoprolol: Hypertention, Arrhythmias, Angina, Migraine, Prophylaxix of myocardial infarction, Indication of Cilnidipine: Hypertention with or without Cardiac failure ii. India	1. There is no scientific justification for combination of two salts of the same molecule (Metoprolol) in an FDC. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
78	S.O. 782(E)	Cilnidipine + metroprolol succinate + metroprolol tartrate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 783(E)	L-Arginine + Sildenafil	-	-	-	-	1. Therapeutic indication for this FDC is not clear. 2. The Subcommittee observed that this FDC is irrational as there is no scientific study to prove the therapeutic benefit of L-arginine in combination with sildenafil. There is no convincing scientific/ clinical evidence/ justification for the FDC.
79	S.O. 783(E)	L-Arginine + Sildenafil	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 784(E)	Atorvastatin + vitamin D3 + folic acid + vitamin B12 + pyridoxine	-	-	-	-	1. This FDC has multiple ingredients. This combination is irrational. 2. There is no information regarding indications. 3. This combination is not as per standard therapeutic guidelines. There is no scientific/ clinical evidence available for this FDC.
80	S.O. 784(E)	Atorvastatin + vitamin D3 + folic acid + vitamin B12 + pyridoxine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 785(E)	Metformin+ Atorvastatin	Akums Drugs	Metformin HCl IP (SR) 500mg+ Atorvastatin Calcium IP eq. To Atorvastatin 10mg film coated tablet	As adjuvant therapy to diet and exercise in patients with diabetic dyslipidemia.	i. Not Submitted ii. Not Submitted	The Subcommittee noted that FDC of Atorvastatin + Metformin (10mg + 500mg SR) Tablets is already approved by CDSCO for the indication : as adjunctive therapy to diet and exercise in patients with diabetic dyslipidemia on 04.12.08 . This FDC was discussed earlier by "10 expert Committee" on 27.08.14 as under- "The committee opined that there is no advantage of proposed fixed dose combination of Atorvastatin and Metformin." The Subcommittee noted the "10 expert Committee" comments and concurred with them. Further, the Subcommittee observed that : 1. This FDC is not appropriate for the indications stated by the company (diabetic dyslipidemia), as the role of Metformin in diabetic dyslipidemia is inconclusive. 2. The dose of Atorvastatin depends on the clinical condition and risk factors and accordingly, the dose may range from 10 mg to 80 mg. Similarly, dose of Metformin also needs to be separately titrated. Such titartion of dose of individual drugs is not feasible with this FDC. 3. Both drugs have different dosing schedules. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 785(E)	Metformin+ Atorvastatin	GKM New Pharma	Metformin HCL IP 1000mg (SR) +Atorvastatin Calcium IP eq. to Atorvastatin 10mg/20mg film coated bilayer tablet	for the treatment of diabetic dyslipidemia.	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: It is stated as always consult your doctor before taking this medicine. Do not stop taking the medications without a physicians advise. ii.Not Submitted	The Subcommittee noted that FDC of Atorvastatin+ Metformin (10mg+ 500mg SR) Tablets is already approved by CDSCO for the indication : as adjunctive therapy to diet and exercise in patients with diabetic dyslipidemia on 04.12.08 . This FDC was discussed earlier by "10 expert Committee" on 27.08.14 as under: "The committee opined that there is no advantage of proposed fixed dose combination of Atorvastatin and Metformin." The Subcommittee noted the "10 expert Committee" comments and concurred with those comments. Further, the Subcommittee observed that : 1. The FDC is not appropriate for the indications stated by the company (diabetic dyslipidemia), as the role of Metformin in diabetic dyslipidemia is inconclusive. 2. The dose of Atorvastatin depends on the clinical condition and risk factors and accordingly, the dose may range from 10 mg to 80 mg. Similarly, dose of Metformin also needs to be separately titrated. Such titartion of dose of individual drugs is not feasible with this FDC. 3. Both drugs have different dosing schedules. There is no sound scientific/ clinical evidence/ justification for the FDC.
81	S.O. 785(E)	Metformin+ Atorvastatin	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 786(E)	Clindamycin+ Telmisartan	-	-	-	-	1. Use of antibiotic (Clindamycin) with angiotensin receptor blocker (Telmisartan) is irrational as the indications for both the ingredients are different. 2. This combination is not as per standard therapeutic guidelines. There is no scientific/ clinical evidence/ justification for the FDC.
22	S.O. 786(E)	Clindamycin+ Telmisartan	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 787(E)	Olmesartan+ Hydrochlorothiazide + Chlorthalidone	-	-	-	-	1. Combination of two drugs from Thiazide diuretics group has no additive benefits and is not recommended in any guideline/published scientific literature. 2. This combination is not as per standard therapeutic guidelines. There is no scientific/ clinical evidence/ justification for the FDC. This FDC is irrational.
83	S.O. 787(E)	Olmesartan+ Hydrochlorothiazide + Chlorthalidone	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 788 (E)	L-5-Methylterahydrofolate calcium + Escitalopram	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification of this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				
84	S.O. 788 (B)	L-5-Methylterahydrofolate calcium + Escitalopram	-	-	-	-	1. No supporting published literature available on the combination. 2. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 789(E)	Pholcodine+ Promethazine	Abbott Healthcare	Pholcodine IP 1.5mg+ Promethazine HCl IP 1.5mg per 5ml syrup	Symptomatic relief of dry cough	i) Indication same as Annexure-A ii) i) Marketed :South Africa ii) Approved : iii) Approved as IND : iv) withdrawn, if any, with reasons : UK withdrawn by company but other similar combinations continue to be available including as OTC.	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee noted that this FDC was approved in 2001 (earlier Promethazine+ Pholcodine+ Phenylpropanolamine was approved prior to 1988). Subcommittee also noted the review and comments by MHRA on anti-tussives including Promethazine and Pholcodine (2009) prohibiting their use in children below 6 years of age. Subcommittee also noted that company's response in Annexure A for regulatory status in other countries is "none" / South Africa and withdrawn in UK. Further: 1. There is no rationale for combining Pholcodine+ Promethazine for the treatment of dry cough (to be given three to four times a day). 2. Pholcodine and Promethazine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 789(E)	Pholcodine+ Promethazine	Mankind Healthcare	Pholcodine IP 1.5mg+ Promethazine HCl IP 1.5mg per 5ml syrup	Indicated for the temporary relief of cough and upper respiratory symptoms associated with allergy or the common cold.	i) Indication same as Annexure-A ii) Not Approved	The subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee noted that this FDC was approved in 2001 (earlier Promethazine+ Pholcodine+ Phenylpropanolamine was approved prior to 1988). Subcommittee also noted the review and comments by MHRA on anti-tussives including Promethazine and Pholcodine (2009) prohibiting their use in children below 6 years of age. Subcommittee also noted that company's response in Annexure A for regulatory status in other countries is "none" / South Africa and withdrawn in UK. Further: 1. There is no rationale for combining Pholcodine+ Promethazine for the treatment of dry cough (to be given three to four times a day). 2. Pholcodine and Promethazine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 789(E)	Pholcodine+ Promethazine	Acron Pharmaceuticls	Pholcodine IP 1.5mg+ Promethazine HCl IP 1.5mg per 5ml oral syrup	Indicated for symptomatic treatment of dry and irritating cough	i) Package insert has not submitted. ii) Not Mentioned	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee noted that this FDC was approved in 2001 (earlier Promethazine+ Pholcodine+ Phenylpropanolamine was approved prior to 1988). Subcommittee also noted the review and comments by MHRA on anti-tussives including Promethazine and Pholcodine (2009) prohibiting their use in children below 6 years of age. Subcommittee also noted that company's response in Annexure A for regulatory status in other countries is "none" / South Africa and withdrawn in UK. Further: 1. There is no rationale for combining Pholcodine+ Promethazine for the treatment of dry cough (to be given three to four times a day). 2. Pholcodine and Promethazine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 789(E)	Pholcodine+ Promethazine	Varav Biogenesis	Pholcodine IP 1.5mg+ Promethazine HCl IP 1.5mg per 5ml syrup	Cough relief for children	i) Indications mentioned in annxeure-A is different form the package insert. Package insert includes relieve form the symptoms of colds in children and is especially useful for irritating night coughs. This formulated cough medicine is suitable for children aged between 2 and 10 years and is a night time formulation , aiding a good night's sleep. ii) Not Submitted	The subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that this FDC was approved in 2001 (earlier Promethazine+ Pholcodine+ Phenylpropanolamine was approved prior to 1988). Subcommittee also noted the review and comments by MHRA on anti-tussives including Promethazine and Pholcodine (2009) prohibiting their use in children below 6 years of age. Subcommittee also noted that company's response in Annexure A for regulatory status in other countries is "none" / South Africa and withdrawn in UK. Further: 1. There is no rationale for combining Pholcodine+ Promethazine for the treatment of dry cough (to be given three to four times a day). 2. Pholcodine and Promethazine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 789(E)	Pholcodine+ Promethazine	Biogenetic	Promethazine HCL IP 1.5 mg+ Pholcodine IP 1.5mg per 5ml syrup	Broad spectrum antibiotic	i. Not Submitted ii. Not Submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee noted that this FDC was approved in 2001 (earlier Promethazine+ Pholcodine+ Phenylpropanolamine was approved prior to 1988). Subcommittee also noted the review and comments by MHRA on anti-tussives including Promethazine and Pholcodine (2009) prohibiting their use in children below 6 years of age. Subcommittee also noted that company's response in Annexure A for regulatory status in other countries is "none" / South Africa and withdrawn in UK. Further: 1. There is no rationale for combining Pholcodine+ Promethazine (to be given three to four times a day). 2.No condition has been specified; instead classified under wrong therapeutic category 3. Pholcodine and Promethazine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
85	S.O. 789(E)	Pholcodine+ Promethazine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 790 (E)	Paracetamol + Promethazine	Ind-Swift Ltd.,	Paracetamol IP 125mg+Promethazine HCl IP 5mg per 5ml Syrup	Relief of mild to moderate pain including headache, toothache, sore throat, aches and pains. For the symptomatic relief of influenza, feverishness ,feverish colds. For the reduction of nasal irritation and watery discharge	i) same as Annexure A ii) Not approved	1. Indications listed by the firm are varied and for these conditions two drugs are not required. Paracetamol alone is effective. Promethazine has no role in any of these symptoms including common cold. 2. Patients do not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. 3. Promethazine possesses sedative properties and may cause respiratory depression especially in children. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 790 (E)	Paracetamol +Promethazine	Mascot Healthcare	Paracetamol IP 125mg+Promethazine HCl IP 5mg per 5ml Syrup	Relief of mild to moderate pain including headache, toothache, sore throat, achesand pains. For the symptomatic relief of influenza, feverishness ,feverish colds. For the reduction of nasal irritation and watery discharge.For the relief of the symptoms of chicken pox.	i) Indications claimed in Package Insert are as follows Indications for paracetamol: 1.To relieve pain and fever 2. Acute gout.3.Migraine. Indications for promethazine:1. Motion sickness 2.Nausea 3.Sedation 4. Allergy. 5. Migraine 6.Vertigo. 7. Anticough ingredient. 8. Anesthetic adjunct ii) Not approved	1. Indications listed by the firm are varied and for these conditions two drugs are not required. Paracetamol alone is effective. Promethazine has no role in any of these symptoms including common cold. 2. Patients do not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. 3. Promethazine possesses sedative properties and may cause respiratory depression especially in children. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 790 (E)	Paracetamol + Promethazine	Kuemen Laboratories	Paracetamol IP 125mg+Promethazine HCl 2.5mg per 5ml syrup	As directed by Physician.	i) Not submitted ii) Not approved	1. Patients do not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. 2. Promethazine possesses sedative properties and may cause respiratory depression especially in children. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 790 (E)	Paracetamol + Promethazine	Skymap Pharmaceutical	Paracetamol IP 125mg+Promethazine HCl IP 5mg per 5ml syrup	Analgesic	i) Not submitted ii) Not submitted	1. For indications listed by the firm, Paracetamol alone is effective. Promethazine has no role. 2. Patients do not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. 3. Promethazine possesses sedative properties and may cause respiratory depression especially in children. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 790 (E)	Paracetamol + Promethazine	Varav Biogenesis	Paracetamol IP 125mg+Promethazine HCl IP 2.5mg per 5ml suspension	Analgesic, Antipyretic and Decongestant.	i) Relieve nasal congestion, sinus sneezing runny nose, pain of colds, fever and pain ii) Not submitted	1. Indications listed by the firm are varied and for these conditions two drugs are not required. Paracetamol alone is effective. Promethazine has no role including as decongestant. 2. Patients do not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. 3. Promethazine possesses sedative properties and may cause respiratory depression especially in children. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 790 (E)	Paracetamol +Promethazine	DM Pharma	Paracetamol IP 125mg+Promethazine Hcl IP 2.5mg per 5ml syrup	Allergic rhinitis	i) Indication mentioned in package insert is different from above. Indications mentioned in package insert are: For the treatment of lower respiratory infection, sinusitis, UTI and is indicated for the relief of mild to moderate pain associated fever. ii) Not submitted	1. Patients do not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. 2. Promethazine possesses sedative properties and may cause respiratory depression especially in children. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 790 (E)	Paracetamol + Promethazine	Meridian Medicare	Paracetamol IP 125mg+Promethazine Hcl IP 2.5mg per 5ml syrup	Painkiller, NSAID, Analgesic, Antipyretic, Anti inflammatory, Nausea, Vomiting, sleeplessness	i) Not submitted ii) Not submitted	1. Indications listed by the firm are varied and for these conditions two drugs are not required. 2. Patients do not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. 3. Promethazine possesses sedative properties and may cause respiratory depression especially in children. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 790 (E)	Paracetamol + Promethazine	Mefro Organics Ltd.	Paracetamol IP 125mg+Promethazine HCl IP 2.5mg per 5ml Syrup	pain, sore throat, feverish cold and flu, Headache	i) same as Annexure A ii) Not approved	1. Indications listed by the firm are varied and for these conditions two drugs are not required. Paracetamol alone is effective. Promethazine has no role in any of these symptoms including "flu". 2. Patients do not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to the other ingredient and its side effects. 3. Promethazine possesses sedative properties and may cause respiratory depression especially in children. There is no sound scientific/ clinical evidence/ justification for the FDC.
86	S.O. 790 (E)	Paracetamol + Promethazine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 791 (E)	Betahistine + Ginkgo Biloba Extract+ Vinpocetine+ Piracetam	-	-	-	-	1. The combination is irrational as there is no proven indication for use of all four drugs together. There is no convincing scientific/ clinical evidence/ justification for the FDC
87	S.O. 791 (E)	Betahistine + Ginkgo Biloba Extract+ Vinpocetine+ Piracetam	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification of this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 792(E)	Cetirizine Dihydrochloride + Diethyl Carbamazine	Unisan Pharmaceuticals	Diethylcarbamazine citrate 300mg + Cetrizine Dihydrochloride 10mg tablet	Tropical Pulmonary Eosinophilia (TPE) & Asthma	NA	1. Diethylcarbamazine is indicated in the treatment of Tropical Pulmonary Eosinophillia (TPE) while Cetirizine is anti histaminic drug for treatment of allergic disorders. There is no sound scientific evidence of combining these two drugs. 2. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
88	S.O. 792(E)	Cetirizine Dihydrochloride + Diethyl Carbamazine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 793(E)	Doxylamine + Pyridoxine + MefenamicAcid+ Paracetamol	-	-	-	-	1. No published literature supporting the FDC for any particular indication. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
89	S.O. 793(E)	Doxylamine + Pyridoxine + MefenamicAcid+ Paracetamol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 794(E)	Drotaverine + Clidinium + Chlordiazepoxide	Aeon Formulations	Drotaverine HCl 80mg+ Clidinium Bromide USP 2.5mg + Chlordiazepoxide IP 5mg film coated tablet	Irritable bowel syndrome	i) same as Annexure A ii) Not submitted	This FDC was earlier discussed by previous Committee on 05.09.2014 as under- "There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend." The Subcommittee concurs with above comments and further notes that: 1. Heterogeneity of clinical presentation of IBS precludes the blanket use of FDC like this which contain two anti spasmodics (Clidinium Bromide and Drotaverine HCl) and anxiolytic benzodiazepines (Chlordiazepoxide). In reality the treatment of IBS needs to be individualized and availability of this FDC has a potential for misuse. 2. Use of this combination is not mentioned in treatment guidelines of Irritable Bowel Syndrome. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
90	S.O. 794(E)	Drotaverine + Clidinium + Chlordiazepoxide	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 795 (E)	Imipramine + Diazepam	Torrent	Imipramine HCl IP 25mg/25mg+Diazepam IP 2mg/5mg film coated tablet	Indicated for treatment of Depression with co-morbid anxiety.	i) Not submitted ii) Not approved	DTAB Subcommittee noted that the FDC of Imipramine + Diazepam is licensed pre 1988. The comments of Subcommittee are as under: 1. Imipramine is antidepressant which is recommended for prolonged use in depression while Diazepam is an anti-anxiety drug which is recommended for very short duration as it has got adverse side effects and abuse potential. Hence this FDC is irrational. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 795 (E)	Imipramine + Diazepam	Micro	Imipramine HCl IP 25mg + Diazepam IP 5mg sugar coated tablet	reducing the symptoms of co-morbid anxiety and depression.	i) same as Annexure A ii) Not approved	DTAB Subcommittee noted that the FDC of Imipramine + Diazepam is licensed pre 1988. The comments of Subcommittee are as under: 1. Imipramine is antidepressant which is recommended for prolonged use in depression while Diazepam is an anti-anxiety drug which is recommended for very short duration as it has got adverse side effects and abuse potential. Hence this FDC is irrational. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 795 (E)	Imipramine + Diazepam	Intas Pharmaceuticals	Imipramine HCl IP 25mg/25mg+Diazepam IP 2mg/5mg film coated tablet	Treatment of depression with co-morbid anxiety.	i) same as Annexure A ii) Not approved	DTAB Subcommittee noted that the FDC of Imipramine + Diazepam is licensed pre 1988. The comments of Subcommittee are as under: 1. Imipramine is antidepressant which is recommended for prolonged use in depression while Diazepam is an anti-anxiety drug which is recommended for very short duration as it has got adverse side effects and abuse potential. Hence this FDC is irrational. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 795 (E)	Imipramine + Diazepam	Intas Pharmaceuticals	Imipramine HCl IP 25mg/25mg+Diazepam IP 2mg/5mg film coated tablet	Treatment of depression with co-morbid anxiety.	i) same as Annexure A ii) Not approved	DTAB Subcommittee noted that the FDC of Imipramine + Diazepam is licensed pre 1988. The comments of Subcommittee are as under: 1. Imipramine is antidepressant which is recommended for prolonged use in depression while Diazepam is an anti-anxiety drug which is recommended for very short duration as it has got adverse side effects and abuse potential. Hence this FDC is irrational. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 795 (E)	Imipramine + Diazepam	LA Pharma	Imipramine HCl 25mg/25mg+Diazepam 5mg/2mg film caoted tablet	Anxiolytics, Antidepressants	i) Not submitted ii) Not submitted	DTAB Subcommittee noted that the FDC of Imipramine + Diazepam is licensed pre 1988. The comments of Subcommittee are as under: 1. Imipramine is antidepressant which is recommended for prolonged use in depression while Diazepam is an anti-anxiety drug which is recommended for very short duration as it has got adverse side effects and abuse potential. Hence this FDC is irrational. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 795 (E)	Imipramine + Diazepam	Manas Pharma	Imipramine HCl IP 25mg/25mg+Diazepam IP 2mg/5mg	Not submitted	i) Not submitted ii) Not submitted	DTAB Subcommittee noted that the FDC of Imipramine + Diazepam is licensed pre 1988. The comments of Subcommittee are as under: 1. Imipramine is antidepressant which is recommended for prolonged use in depression while Diazepam is an anti-anxiety drug which is recommended for very short duration as it has got adverse side effects and abuse potential. Hence this FDC is irrational. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 795 (E)	Imipramine + Diazepam	Heilmittel Pharmaceuticals	Imipramine HCl IP 25mg+Diazepam IP 2mg film coated tablet	Control Nocturnal enuresis, anxiety nervous tension to relieve muscle spasm	i) Not submitted ii) Not submitted	DTAB Subcommittee noted that the FDC of Imipramine + Diazepam is licensed pre 1988. The comments of Subcommittee are as under: 1. Imipramine is antidepressant which is recommended for prolonged use in depression while Diazepam is an anti-anxiety drug which is recommended for very short duration as it has got adverse side effects and abuse potential. Hence this FDC is irrational. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
91	S.O. 795 (E)	Imipramine + Diazepam	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 796 (E)	Flupentixol +Escitalopram	Magnet	Flupentixol Dihydrochloride BP eq. To Flupentixol 0.5mg+Escitalopram Oxalate IP eq. To Escitalopram 10mg film coated tablet	for treatment of Co-morbid anxiety & depression	i) same as Annexure A ii) Not approved	1. Treatment guidelines do not mention use of antidepressant and neuroleptic for co-morbid depression and anxiety. 2. There is a likelihood of increased risk of serious ADRs. Both drugs can cause QTc prolongation and should not be combined. 3. Further, both drugs can lower seizure threshold. 4. Escitalopram can also inhibit metabolism of flupentixol, increasing the risk of toxicity with flupentixol. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 796 (E)	Flupentixol + Escitalopram	Micro	Flupentixol HCl BP eq. To Flupentixol 0.5mg+Escitalopram Oxalate IP eq. To Escitalopram 10mg film coated tablet	for reducing the symptoms of co-morbid anxiety and depression.	i) same as Annexure A ii) Not approved	1. Treatment guidelines do not mention use of antidepressant and neuroleptic for co-morbid depression and anxiety. 2. There is a likelihood of increased risk of serious ADRs. Both drugs can cause QTc prolongation and should not be combined. 3. Further, both drugs can lower seizure threshold. 4. Escitalopram can also inhibit metabolism of flupentixol, increasing the risk of toxicity with flupentixol. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 796 (E)	Flupentixol + Escitalopram	Akums Drugs	Flupentixol HCl BP eq. to Flupenthixol 0.5mg+Escitalopram Oxalate IP eq. to Escitalopram 10mg film coated tablet	for treatment of major depressive episodes, schizophrenia and other psychosis.	i) Not submitted ii) Not approved	1. Treatment guidelines do not mention use of antidepressant and neuroleptic for depression and psychosis. 2. There is a likelihood of increased risk of serious ADRs. Both drugs can cause QTc prolongation and should not be combined. 3. Further, both drugs can lower seizure threshold. 4. Escitalopram can also inhibit metabolism of flupentixol, increasing the risk of toxicity with flupentixol. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 796 (E)	Flupentixol + Escitalopram	Obsurge Biotech Ltd.	Flupentixol dihydrochloride BP eq. to Flupenthicol 0.5mg+Escitalopram Oxalate IP eq. to Escitalopram 10mg tablet	for treatment of anxiety and depression	i) Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Neuroleptic agent related structurally to thiothixene, Antipsychotic; neuroleptic agent, dopamine receptor antagonist. Ii) Not approved	1. Treatment guidelines do not mention use of antidepressant and neuroleptic for depression and anxiety. 2. There is a likelihood of increased risk of serious ADRs. Both drugs can cause QTc prolongation and should not be combined. 3. Further, both drugs can lower seizure threshold. 4. Escitalopram can also inhibit metabolism of flupentixol, increasing the risk of toxicity with flupentixol. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 796 (E)	Flupentixol + Escitalopram	Windlas Biotech	Flupentixol Dihydrochloride BP eq. to Flupenthixol 0.5mg+Escitalopram Oxalate IP eq. to Escitalopram 10mg film coated tablets	For treatment of co-morbid anxiety & Depression.	i) same as Annexure A ii) Not submitted	1. Treatment guidelines do not mention use of antidepressant and neuroleptic for co-morbid depression and anxiety. 2. There is a likelihood of increased risk of serious ADRs. Both drugs can cause QTc prolongation and should not be combined. 3. Further, both drugs can lower seizure threshold. 4. Escitalopram can also inhibit metabolism of flupentixol, increasing the risk of toxicity with flupentixol. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 796 (E)	Flupentixol + Escitalopram	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 797 (E)	Paracetamol + Prochloperazine	Macmillon Pharma	Each tablet contains: Prochlorperazine 5mg Paracetamol 650mg	Symptomatic treatment of headache with nausea/ vomiting due to migraine.	i Indications same as Annexure A ii Not mentioned	The Subcommittee noted that the kokate committee has reviewed a FDC containing Paracetamol + Prochlorperazine maleate (S.O. 741) and commented as under: "The kokate committee observed that the FDC was categorized as 'a' i.e. irrational, inadvertently in the report due to typographical error, as similar FDCs have been considered as rational at S. No's 270 and 1376 of the committee report. Therefore the committee recommends that FDC of Paracetamol + Prochlorperazine shall be considered as rational". The DTAB Subcommittee noted that this FDC contains Paracetamol + Prochlorperazine which is same as S.O. 741 and noted that: 1. Treatment guidelines mention use of Paracetamol and Prochlorperazine in acute attack of migraine. The Subcommittee opined that the FDC of Paracetamol and Prochlorperazine in usual therapeutic doses is rational for the treatment of acute migraine attack only. It recommends that the use of this FDC (Paracetamol 500/650 mg + Prochlorperazine 5 mg) shall be restricted "for treatment of acute migraine attack associated with nausea and/ or vomiting in adults only".
93	S.O. 797 (E)	Paracetamol + Prochloperazine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **The use of this FDC is rational but that the use of this FDC (Paracetamol 650 mg + Prochlorperazine 5 mg) shall be restricted "for treatment of acute migraine attack only associated with nausea and/ or vomiting in adults".** **Hence in the larger public interest, it is necessary to restrict the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 798 (E)	Gabapentin + Mecobalamin + Pyridoxine + Thiamine	-	-	-	-	There is no company representation and no information regarding the indication for which this FDC is to be used. 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and side effect (of Gabapentin). 2. It increases the probability of unnecessary vitamin supplementation. There is no convincing scientific/ clinical evidence/ justification for the FDC.
94	S.O. 798 (E)	Gabapentin + Mecobalamin + Pyridoxine + Thiamine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 799(E)	Imipramine + Chlordiazepoxide + Trifluoperazine + Trihexyphenidyl	-	-	-	-	The Subcommittee noted the comments of Kokate committee as under: "Pharmacodynamically irrelevant- 1.Trifluoperazine and Imipramine both increase QTc interval. 2. High likelihood of serious or life-threatening interaction. 3.Trihexyphenidyl and Imipramine both decrease cholinergic effects/transmission. 4.Chlordiazepoxide and Trifluoperazine both increase sedation. 5.Trihexyphenidyl decreases levels of trifluoperazine by pharmacodynamic antagonism." The Subcommittee concured with the above and further opined that : 1. The combination is irrational as there is no proven indication for use of all four drugs together. There is no convincing scientific/ clinical evidence/ justification for the FDC.
95	S.O. 799(E)	Imipramine + Chlordiazepoxide + Trifluoperazine + Trihexyphenidyl	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 800(E)	Chlorpromazine +Trihexyphenidyl	-	-	-	-	1. No proven therapeutic benefit. Trihexyphenidyl may alter Chlorpromazine level by Pharmacokinetic interaction. 2. Trihexiphenyl dosage cannot be adjusted as per requirement in FDC. 3. Anticholinergic side effects will be precipitated by this combination because of additive anticholiergic action. Anticholinergic effect can promote cognitive impairement in long term use. There is no convincing scientific/ clinical evidence/ justification for the FDC.
96	S.O. 800(E)	Chlorpromazine +Trihexyphenidyl	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	Lupin	Ursodeoxycholic Acid IP 300mg+ Silymarin 140mg film coated tablet	For the treatment of patients with primary biliary cirrhosis (PBC)	i) same as Annexure A ii) Not submitted	1. Ursodeoxycholic Acid (UDCA) is a first line pharmacotherapy for all patients with primary biliary cirrhosis (PBC). 2. Silymarin is not indicated in PBC and therefore does not provide any additional benefit. It will only add to ADR and cost. 3. This combination is not as per standard therapeutic guidelines for the indications mentioned. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	Macleods	Ursodeoxycholic Acid BP 300mg+ Silymarin 140mg film coated tablet	Supportive treatment in chronic liver disease.	i) same as Annexure A ii) Not submitted	1. Ursodeoxycholic Acid (UDCA) is a first line pharmacotherapy for all patients with primary biliary cirrhosis (PBC). 2. Silymarin is not indicated in PBC and therefore does not provide any additional benefit. It will only add to ADR and cost. 3. This combination is not as per standard therapeutic guidelines for the indications mentioned. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	Akums Drugs	Ursodeoxycholic Acid BP 300mg+ Silymarin 140mg film coated tablet	Chronic liver disease, Primary biliary cirrhosis and prevents liver to form toxins	i) same as Annexure A ii) Not submitted	1. Ursodeoxycholic Acid (UDCA) is a first line pharmacotherapy for all patients with primary biliary cirrhosis (PBC). 2. Silymarin is not indicated in PBC and therefore does not provide any additional benefit. It will only add to ADR and cost. 3. This combination is not as per standard therapeutic guidelines for the indications mentioned. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	GKM New Pharma	Ursodeoxycholic Acid 300mg+ Silymarin 140mg tablet	For the treatment of imporved liver function, Cirrhosis, Gallstone, Gall bladder disorders, Hepatic disorder, High blood sugar	i) same as Annexure A ii) Not approved	1. Ursodeoxycholic Acid (UDCA) is a first line pharmacotherapy for all patients with primary biliary cirrhosis (PBC). 2. Silymarin is not indicated in PBC and therefore does not provide any additional benefit. It will only add to ADR and cost. 3. This combination is not as per standard therapeutic guidelines for the indications mentioned. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	GKM New Pharma	Ursodeoxycholic Acid 150mg+ Silymarin 70mg tablet	For the treatment of imporved liver function, Cirrhosis, Gallstone, Gall bladder disorders, Hepatic disorder, High blood sugar	i) same as Annexure A ii) Not approved	1. Ursodeoxycholic Acid (UDCA) is a first line pharmacotherapy for all patients with primary biliary cirrhosis (PBC). 2. Silymarin is not indicated in PBC and therefore does not provide any additional benefit. It will only add to ADR and cost. 3. This combination is not as per standard therapeutic guidelines for the indications mentioned. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	Micro Labs	Ursodeoxycholic Acid BP 300mg+ Silymarin 140mg tablet	As an adjuvant for hepatoprotection in the conditions as Nonalcoholicsteatohepatitis (NASH), Virus associated steatohepatitis (VASH), Drug associated steatohepatitis (DASH), Alcoholic steatohepatitis (ASH) and Cholestatic jaundice.	i) same as Annexure A ii) Not submitted	1. Ursodeoxycholic Acid (UDCA) is a first line pharmacotherapy for all patients with primary biliary cirrhosis (PBC). 2. Silymarin is not indicated in PBC and therefore does not provide any additional benefit. It will only add to ADR and cost. 3. This combination is not as per standard therapeutic guidelines for the indications mentioned. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	Aeon Formulations	Ursodeoxycholic Acid 300mg/50mg+ Silymarin 140mg/35mg tablet	Dissolution of cholesterol-rich gallstones, Primary biliary cirrhosis, Hepatic diseases	i) same as Annexure A ii) Not submitted	1. Ursodeoxycholic Acid (UDCA) is a first line pharmacotherapy for all patients with primary biliary cirrhosis (PBC). 2. Silymarin is not indicated in PBC and therefore does not provide any additional benefit. It will only add to ADR and cost. 3. This combination is not as per standard therapeutic guidelines for the indications mentioned. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	Pharmed Ltd.	Ursodeoxycholic Acid + Silymarin	Indicated in which this product is proposed to be are acute and chronic liver disease where hepatotoxicity is major underlying mechanism leading to injury of hepatic cell such as a) Non- alcoholic fatty liver disease b) Alcoholic fatty liver disease c) cholestasis liver disease d) primary biliary cirrhosis e) Acute and chronic viral hepatitis f) toxic and iatrogenic liver disease.	i) same as Annexure A ii) Not submitted	1. Ursodeoxycholic Acid (UDCA) is a first line pharmacotherapy for all patients with primary biliary cirrhosis (PBC). 2. Silymarin is not indicated in PBC and therefore does not provide any additional benefit. It will only add to ADR and cost. 3. This combination is not as per standard therapeutic guidelines for the indications mentioned. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing any where	
	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	Saichem Pharma	Ursodeoxycholic Acid 300mg+ Silymarin 140mg tablet	The indications in which this product is proposed to be are acute and chronic liver diseases, where hepatotoxicity is the major underlying mechanism leading to injury of hepatic cells such as, a) Non-alcoholic fatty liver disease (NAFLD) b) Alcoholic fatty liver disease (AFLD) c) Cholestatic liver diseases d) Primary biliary cirrhosis e) Acute and chronic viral hepatitis f) Toxic and iatrogenic liver diseases	i) same as Annexure A ii) Not submitted	1. Ursodeoxycholic Acid (UDCA) is a first line pharmacotherapy for all patients with primary biliary cirrhosis (PBC). 2. Silymarin is not indicated in PBC and therefore does not provide any additional benefit. It will only add to ADR and cost. 3. This combination is not as per standard therapeutic guidelines for the indications mentioned. There is no sound scientific/ clinical evidence/ justification for the FDC.
97	S.O. 801(E)	Ursodeoxycholic Acid + Silymarin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**					

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg+ Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg+ Glimepiride 1/ 2/ 1/ 2mg	Accent Pharma	Metformin HCl (Sustained release) 500mg+ Pioglitazone HCl 7.5mg+ Glimepiride 1mg tablet	Mentioned that will be submitted in due course.	i. Indication is not mentioned in package insert. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg) + Pioglitazone (15mg)+ Metformin (500mg ER) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under: "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in the FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg+ Metformin HCl 500mg(SR)+ Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendations of the "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1 / 2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Cipla Ltd.	Metformin HCl (SR) 500/ 500mg+ Pioglitazone HCl eq. to Pioglitazone 7.5/ 7.5mg+ Glimepiride 1mg/ 2mg tablet	As per pack insert	i. Used as once per day, is indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycemic control in patients with type-2 diabetes. It is not intended to use as first line treatment ii. Not submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg ER) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies, one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg (SR)+ Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Accent Pharma	Metformin HCl (SR) 500mg+ Pioglitazone HCl eq. to Pioglitazone 7.5mg+ Glimepiride 2mg tablet	Mentioned that will be submitted in due course.	i. Indication is not mentioned in package insert. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg ER) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under: "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg+ Metformin HCl 500mg (SR)+ Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg dose of Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Madras Pharma	Metformin HCl (SR) 500mg+ Pioglitazone HCl eq. to Pioglitazone 7.5mg+ Glimepiride 1mg tablet	It is indicated as an adjunct to diet, exercise to lower blood glucose. It is indicated as second-line therapy when, diet, exercise, the single agents and dual combination therapy do not result in adequate glycemic control in patient with type-2 diabetes.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg+ Metformin HCl 500mg (SR)+ Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg+ Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg+ Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg+ Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Inventia Healthcare	Metformin Hydrochloride IP 500mg (in sustained release form)+Pioglitazone 7.5mg + Glimepiride IP 1mg uncoated bilayered tablet	The proposed FDC is indicated for 3rd line therapy treatment of Type-II diabetes mellitus, when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control.	i. Indicated once daily as adjunct to diet and exercise after Metformin failure or after dual therapy do not result in adequate glycaemic control in patients with type-2 diabetes. ii. Not submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg ER) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under: "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg+ Metformin HCl 500mg (SR)+ Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1/ 2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg+ Glimepiride 1/ 2/ 1/ 2mg	Inventia Healthcare	Metformin Hydrochloride IP 500mg (in sustained release form)+ Pioglitazone 7.5mg+ Glimepiride IP 2mg uncoated bilayered tablet	As 3rd line treatment of Type II diabetes mellitus who diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control.	i. Indicated once daily, as an adjuanct to diet and exercise, to lower blood glucose. It is indicated as second-line therapy when diet, exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type II diabetes. Further this FDC should not be used as first line therapy for diabetes. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg)+ Pioglitazone (15mg)+ Metformin (500mg ER) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under: "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR)+ Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee consideres the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg+ Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/2/ 1/2mg	Sun Pharma	Metformin HCl IP ER 500/ 500mg +Pioglitazone HCl 7.5mg/ 7.5mg+ Glimepiride 1mg/ 2mg uncoated bilayered tablet	The proposed FDC should not be used as first line therapy for diabetes. The proposed FDC is indicated for 3rd line therapy treatment of Type-II diabetes mellitus, when diet, exercise and the single agents and second line therapy with drugs do not result in adequate glycemic control.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg+ Metformin HCl 500mg(SR)+ Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendations of the "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1/ 2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg+ Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Systopic Laboratories	Metformin HCl IP SR 500mg+ Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Glimepiride 1mg uncoated bilayered tablet	As 3rd line treatment of Type II diabetes mellitus who diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: It is indicated once daily, as an adjunct to diet and exercise, to lower blood glucose. It is indicated as second-line therapy when diet, exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type II diabetes. ii. Not submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg ER) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg+ Metformin HCl 500mg(SR)+ Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1/ 2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and bearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg+ Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1/ 2mg	Systopic Laboratories	Metformin HCl IP SR 500mg+ Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Glimepiride 2mg uncoated bilayered tablet	As 3rd line treatment of Type II diabetes mellitus who diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: It is indicated once daily, as an adjunct to diet and exercise, to lower blood glucose. It is indicated as second-line therapy when diet, exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type II diabetes. ii. Not submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under: "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg+ Metformin HCl 500mg (SR)+ Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/2/1/2mg	Unison Pharmaceuticals	Metformin HCl IP 500mg/ 500mg (SR form)+ Pioglitazone HCl IP eq. to Pioglitazone 7.5mg/ 7.5mg+ Glimepiride IP 1mg/ 2mg uncoated bilayered tablet	The tablet is indicated once daily, as an adjunct to diet, exercise and to lower blood glucose. It is indicated as 2nd line therapy treatment, when diet, exercise and the single agents and dual therapy do not result in adequate glycemic control in patient with type-2 diabetes mellitus.	i. Indications not clearly defined. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1/ 2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and anatysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Franco-Indian	Metformin HCl IP (SR) 500mg+ Pioglitazone HCl eq. To Pioglitazone 7.5mg+ Glimepiride IP 1mg uncoated bilayered tablet	Used as an adjunct to diet and exercise to lower blood glucose. It is indicated as second line therapy when diet,exercise,single agents and dual combination therapy do not result in adequate glycaemic control in patients with type 2 diabetes.In patients with type 2 diabetes. As adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Concomitantly: with insulin to improve glycemic control in adults (17 years of age and older)(indication as per Package Insert)	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg ER) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concured with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1/ 2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/2/1/2mg	Lupin	Glimepiride 2mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+ Metformin HCl IP 500mg uncaoted bilayered tablet	As third line treatment of Type II diabetes mellitus in adult patients when diet, exercise and the singe agents and second line therapy with two drugs do not result in adequate glycemic control	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	I) Indicaiton as per package insert II) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Madras Pharma	Metformin Hydrochloride IP (sustained release form) 500 mg+ Pioglitazone Hydrochloride eq. To Pioglitazone 7.5 mg + Glimepiride IP 2 mg	This tablet is indicated as an adjunct to diet and exercise, to lower blood glucose. It is indicated as second-line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycaemia control in patients with type 2 diabetes.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg+ Glimepiride 1/2/1/2mg	Macleods	Glimepiride IP 1mg/ 2mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg/ 7.5mg+ Metformin HCl IP 500mg/ 500mg (SR) uncoated bilayered tablet	For treatment of Type 2 diabetes mellitus	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Franco-Indian	Glimepiride IP 2mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+ Metformin HCl IP 500mg (SR) uncoated bilayered tablet	Used as an adjunct to diet and exercise to lower blood glucose. It is indicated as second line therapy when diet,exercise,single agents and dual combination therapy do not result in adequate glycaemic control in patients with type 2 diabetes.in patients with type 2 diabetes. As adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Concomitantly: with insulin to improve glycemic control in adults (17 years of age and older)	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Lupin	Glimepiride IP 1mg+Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+ Metformin HCl IP 500mg uncoated bilayered tablet	As 3rd line treatment of Type-2 Diabetes Mellitus when diet, exercise and the single agents and second line therapy with two drugs do not results in adequate glycemic control.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concured with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Lupin	Glimepiride IP 2mg+Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+Metformin HCl IP 1000mg uncoated bilayered tablet	As 3rd line treatment of Type-2 Diabetes Mellitus when diet, exercise and the single agents and second line therapy with two drugs do not results in adequate glycemic control.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2 /1/ 2mg	Eris Lifesciences	Glimepiride IP 2mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+ Metformin HCl IP 1000mg (SR) uncoated bilayered tablet	Used as an adjuvant to diet and exercise to improve glycemic control in patients with type 2 diabetes who do not achieve glycemic control with diet and exercise alone.It is indicated as second line therapy when diet,exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type 2 diabetes.	i. Not Submitted ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg+ Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Lupin	Glimepiride 1mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+ Metformin HCl IP 1000mg uncoated bilayered tablet	As 3rd line treatment of type 2 diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycaemic control.	i. As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control. Management of type 2 diabetes should also include nutritional counseling, weight reduction as needed, and exercise. These ef forts are important not only in the primary treatment of type 2 diabetes, but also to maintain the ef ficacy of drug therapy. Prior to initiation or escalation of oral antidiabetic therapy in patients with type 2 diabetes mellitus, secondary causes of poor glycemic control, e.g., infection, should be investigated and treated. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1/ 2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Micro	Glimepiride IP 2mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+Metformin HCl IP 500mg (SR) uncoated bilayered tablet	As 3rd line treatment of type 2 diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycaemic control.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Eris Lifesciences	Glimepiride IP 2mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+ Metformin HCl IP 500mg (SR) uncoated bilayered tablet	Triglimisavel is used as an adjutant to diet and exercise to improve glycemic control in patients with type 2 diabetes who do not achieve glycemic control with diet and exercise alone. It is indicated as second line therapy when diet. exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type 2 diabetes.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Eris Lifesciences	Glimepiride IP 1mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+Metformin HCl IP 1000mg (SR) uncoated bilayered tablet	Triglimisavel is used as an adjutant to diet and exercise to improve glycemic control in patients with type 2 diabetes who do not achieve glycemic control with diet and exercise alone. It is indicated as second line therapy when diet. exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type 2 diabetes.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/ 2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Akums Drugs	Glimepiride IP 1mg/2mg+Pioglitazone HCl IP eq. To Pioglitazone 7.5mg/7.5mg+Metformin HCl IP 500mg/500mg uncoated bilayered tablet	Combination is indicated as an adjunct to diet and exercise: To improve glycemic control in patients with type 2 diabetes, or patients whose diabetes is not adequately controlled with glimepiride, Pioglitazone and Metformin alone	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Eris Lifesciences	Glimepiride IP 1mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+Metformin HCl IP 500mg (SR) uncaoted bilayered tablet	Triglimisave LSI is used as an adjutant to diet and exercise to improve glycemic control in patients with type 2 diabetes who do not achieve glycemic control with diet and exercise alone. It is indicated as second line therapy when diet, exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type 2 diabetes.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Micro	Glimepiride IP 1mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+ Metformin HCl IP 500mg (SR) uncaoted bilayered tablet	As 3rd line treatment of type 2 diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycaemic control.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/2/1/2mg	Acme Generics	Glimepiride IP 2mg+ Pioglitazone HCL IP eq. to Pioglitazone 7.5mg+ Metformin HCl IP 500mg uncoated bilayered tablet	Tablets are indicated once daily, as an adjuvant to diet and exercise, to lower blood glucose. It is indicated as second-line therapy when diet, exercise, and the single agents or dual therapy do not result in adequate glycemic control in patients with type-2 diabetes	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Acme Generics	Glimepiride IP 1mg+Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+Metformin Hcl IP (SR) 500mg uncoated bilayered tablets	Metformin Hydrochloride (SR), Pioglitazone Hydrochloride and Glimepiride Tables are indicated as an adjunct to diet and exercise to lower blood glucose. It is indicated as second line therapy when diet exercise, and the single agents or dual therapy do not result in adequate glycemic control in patients with type-2 diabetes.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/ 2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Windlas Biotech	Glimepiride IP 1mg+ Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Metformin Hcl IP (SR) 500mg tablets	It is indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycemic control in patients with Type I diabetes	i. Glimepiride, Pioglitazone and Metformin Tablets are indicated once daily, as an adjuvant to diet and exercise, to lower blood glucose. It is indicated as second-line therapy, when diet, exercise and the single agents or dual therapy do not result in adequate control in patients with type 2 diabetes. ii. Not submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Windlas Biotech	Glimepiride IP 2mg+ Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Metformin Hcl IP (SR) 500mg tablets	It is indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycemic control in patients with Type I diabetes	i. Glimepiride, Pioglitazone and Metformin Tablets are indicated once daily, as an adjuvant to diet and exercise, to lower blood glucose. It is indicated as second-line therapy, when diet, exercise and the single agents or dual therapy do not result in adequate control in patients with type 2 diabetes. ii. Not submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/ 1/ 2mg	Windlas Biotech	Glimepiride IP 2mg+Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Metformin Hcl IP (SR) 1000mg tablets	It is indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycemic control in patients with Type I diabetes	i. Glimepiride, Pioglitazone and Metformin Tablets are indicated once daily, as an adjuvant to diet and exercise, to lower blood glucose. It is indicated as second-line therapy, when diet, exercise and the single agents or dual therapy do not result in adequate control in patients with type 2 diabetes. ii. Not submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	ABS Remedies	Glimepiride IP 2mg+ Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Metformin HCl IP (SR) 500mg tablets	Not Mentioned	i. Not Submitted ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	ACME Generics LLP	Metformin HCl (Sustained release) 1000 mg+ Pioglitazone HCl 7.5mg+ Glimepiride 1mg tablet	As an Adjuct to diet and exercise, to lower blood glucose. It is indicated as scond line therapy when diet, exercise and the single agents or dual therapy control in patients with type-2 diabetes.	i. Not Submitted ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg)+ Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Eris Lifesciences Ltd.	Metformin HCl (Sustained release) 1000 mg+ Pioglitazone HCl 7.5mg+ Glimepiride 1mg tablet	As an Adjuct to diet and exercise, to Improve glycemic control in patienta with type-2 diabetes who do not achieve glycemic control with ddiet and exercise alone. It is indicated as scond line therapy when diet, exercise and th the single agents or dual therapy do not result in adequate glycemice control in patients with type-2 diabetes.	i. Same as Annexure-A ii. Not Submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control by CDSCO on 16.08.2005 The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5mg + Glimepiride 1/ 2/1 /2mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
98	S.O. 802(E)	Metformin 1000/ 1000/ 500/ 500mg + Pioglitazone 7.5/ 7.5/ 7.5/ 7.5 mg + Glimepiride 1/ 2/ 1/ 2mg	Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 803(E)	Gliclazide 80 mg + Metformin 325 mg	-	-	-	-	The dose of Metformin in this FDC is sub-therapeutic. Therefore, this combination is irrational. There is no sound scientific/ clinical evidence/ justification for the FDC
99	S.O. 803(E)	Gliclazide 80 mg + Metformin 325 mg	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 804(E)	Voglibose + Metformin + Chromium Picolinate	-	-	-	-	The current literature is inconclusive about the benefits of Chromium in combination with Metformin. None of the guidelines mention Chromium as first, second or third line agent in treatment of diabetes. Thus, this combination is irrational. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 804(E)	Voglibose + Metformin + Chromium Picolinate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	Lupin	Pioglitazone HCl 7.5mg film coated modified release tablet+Metformin HCl 500mg	As 2nd line treatment of type 2 diabetes mellitus when diet, exercise and single agents do not result in adequate glycemic control.	i. Package insert is unreadable. ii. Not submitted	The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	Eris Lifesciences	Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+ Metformin HCl IP 500mg (SR) uncoated bilayered tablet	It is used as adjunct to diet, exercise to improve glycemic control in patient with of Type-II diabetes mellitus who do not achieve glycemic control with diet, exercise alone. As 2ndline therapy when diet, exercise and the single agents or dual therapy with drugs do not result in adequate glycemic control in patient with type 2 diabetes mellitus.	i. Not Submitted ii. Not Submitted	The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	Eris Lifesciences	Pioglitazone HCl IP eq. To Pioglitazone 7.5mg+ Metformin HCl IP 1000mg (SR) uncoated bilayered tablet	It is used as adjunct to diet, exercise to improve glycemic control in patient with of Type-II diabetes mellitus who do not achieve glycemic control with diet, exercise alone. As 2ndline therapy when diet, exercise and the single agents or dual therapy with drugs do not result in adequate glycemic control in patient with type 2 diabetes mellitus.	i. Not Submitted ii. Not Submitted	The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Pioglitazone 7.5/7.5mg+Metformin 500/1000mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	Franco-Indian	Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Metformin HCl IP 500mg (in sustained relase form) uncoated bilayered tablet	It is used as adjunct to diet, exercise to improve glycemic control in adult with of Type-II diabetes mellitus who are already treated with a combination of Metformin and Pioglitazone, given separately, or whose diabetes is not adequately controller with Metformin alone, or for those patients who have initially responded to Pioglitazone alone and require glycemic control. It is indicated for use in combination with insulin in triple drug therapy is indicated to achieve glycemic control	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Monotherapy:It is used as adjunct to diet, exercise to improve glycemic control in patient with of Type-II diabetes mellitus. Concomitantly: With sulfonylurea and insulin to improve glycaemic control in adults. ii. Not Submitted	The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Pioglitazone 7.5/7.5mg+Metformin 500/1000mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	USV Pvt. Ltd.	Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+Metformin HCL IP 500 (in SR form) uncaoted tablet	It is used as adjunct to diet, exercise to improve glycemic control in patients with of Type-II diabetes mellitus who are already treated with a combination of Metformin and Pioglitazone, given separately, or whose diabetes is not adequately controller with Metformin alone, or for those patients who have initially responded to Pioglitazone alone and require glycemic control.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Pioglitazone 7.5/7.5mg+Metformin 500/1000mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	Madras Pharma	Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+Metformin Hcl IP (SR) 500mg uncoated bilayered tablets	It is used as adjunct to diet, exercise to improve glycemic control in adult with of Type-II diabetes mellitus who are already treated with a combination of Metformin and Pioglitazone, given separately, or whose diabetes is not adequately controller with Metformin alone, or for those patients who have initially responded to Pioglitazone alone and require glycemic control. It is indicated for use in combination with insulin in triple drug therapy is indicated to achieve glycemic control.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Pioglitazone 7.5/7.5mg+Metformin 500/1000mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	Maral Labs	Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Metformin Hcl IP (SR) 500mg uncoated bilayered tablets	Mentioned will be submitted in due course.	i. Indicated for second line therapy for Type-2 diabetes mellitus. This drug should not used first line therapy for diabetes. ii. Not Submmited	The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Pioglitazone 7.5/ 7.5mg+ Metformin 500/1000mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	Windlas Biotech	Pioglitazone 7.5mg+ Metformin 500mg tablets	It is indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycemic control in patients with Type II diabetes	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Pioglitazone 7.5/7.5mg+Metformin 500/1000mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	Next Wave (India)	Pioglitazone HCl IP eq. to Pioglitazone 30mg+ Metformin HCl IP 500mg (in Extended relase form) uncoated bilayered tablet	Piokind-M-30mg Tablet is used in the treatment of type 2 diabetes. It is used in addition to diet and exercise to improve blood sugar control in adults with type 2 diabetes (as per PI:- Pioglitazone and Metformin HCl tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus)	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the strength of Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg, as inappropriate. There is no sound scientific/ clinical evidence/ justification for the FDC.
101	S.O. 805(E)	Pioglitazone 7.5/ 7.5mg+ Metformin 500/ 1000mg	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Tristar Formulations	Metformin HCl (Sustained release) 1000mg+ Pioglitazone HCl 15mg+ Glimepiride 2mg tablet	Mentioned will be submitted in due course.	i. Anti-diabetic. ii. Not submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy. In these patients, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/2mg/3mg+Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Madras Pharma	Metformin HCl (Sustained release) 1000mg+ Pioglitazone HCl 15mg+ Glimepiride 1mg tablet	will be submitted in due course	i. Treatment of Diabetis Mellitus, where diet, physical exercise and weight reduction alone are not adequate. This drug should not be used as first line of therapy of diabeties ii. Not Submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/2mg/3mg+Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/1000mg	Madras Pharma	Metformin HCl (SR) 1000mg+Pioglitazone HCl eq. to Pioglitazone 15mg+Glimepiride 2mg tablet	Mentioned that will be submitted in due course.	i. Treatment of Type-2 diabetes mellitus, when, diet, physical excercise and weight reduction alone are not adequate. This drug should not used first line therapy for diabetes. ii.Not submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/2mg/3mg+Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Meridian Medicare	Metformin 1000mg + Pioglitazone 15mg+ Glimepiride 1mg/ 2mg tablet	The proposed FDC is indicated for 2nd line therapy, when diet, exercise and the single agents or dual therapy with drugs do not result in adequate glycemic control in patient with Type-II diabetes mellitus.	i. Not Submitted ii. Not Submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/ 2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/ 2mg/ 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Sun Pharma Industries	Glimepiride IP 1mg/ 2mg/ 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/15mg+ Metformin Hcl IP (ER) 1000mg/ 1000mg/ 1000mg uncoated bilayered tablets	The proposed FDC should not be used first line therapy for diabetes. It is indicated as 3rd line therapy of type-II diabetes mellitus when, diet, exercise and the single agent and second line therapy with drugs do not results in adequate glycemic control	i. Indication same as Annexure A. ii. USA and UK.	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/2mg/3mg+Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Lupin	Glimepiride IP 1mg+Pioglitazone HCl IP eq. To Pioglitazone 15mg+Metformin HCl IP 1000mg (ER) uncoated tablet	As 3rd line treatment of type 2 diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycaemic control.	i. As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control. Management of type 2 diabetes should also include nutritional counseling, weight reduction as needed, and exercise. These ef forts are important not only in the primary treatment of type 2 diabetes, but also to maintain the ef ficacy of drug therapy. Prior to initiation or escalation of oral antidiabetic therapy in patients with type 2 diabetes mellitus, secondary causes of poor glycemic control, e.g., infection, should be investigated and treated. ii. Not Submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/2mg/3mg+Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Micro	Glimepiride IP 2mg+ Pioglitazone HCl IP eq. To Pioglitazone 15mg+ Metformin HCl IP 1000mg (SR) uncaoted bilayered tablet	As third line treatment of Type 2 diabetes Mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control	i. Indication same as Annexure A. Ii. Not Submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/ 2mg/ 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.
	S.O. 806 (E)	Glimepiride 1mg/2mg/3mg+Pioglitazone 15mg/15mg/15mg+ Metformin 1000mg/1000mg/1000mg	Micro	Glimepiride IP 1mg+Pioglitazone HCl IP eq. To Pioglitazone 15mg+Metformin HCl IP 1000mg (SR) uncaoted bilayered tablet	As third line treatment of Type 2 diabetes Mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control	i. Indication same as Annexure A. Ii. Not Submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/2mg/3mg+Pioglitazone HCl IP eq. to Pioglitazone 15mg/15mg/15mg+Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/1000mg/1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	USV Pvt. Ltd.	Glimepiride IP 2mg (as micronised)+ Pioglitazone HCL IP eq. to Pioglitazone 15mg+ Metformin HCl IP 1000mg (ER form) uncoated bilayered tablet	Pioz MF G-2 Forte/ the triglynase2 forte Tablets are indicated once daily, as an adjunct to diet and exercise, to lower blood glucose. It is indicated as second-line therapy when diet, exercise, and the single agent or dual therapy do not result in adequate glycemic control in patients with type-2 diabetes	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/ 2mg/ 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Tristar Formulations	Glimepiride IP 1mg+Pioglitazone HCl IP eq. to Pioglitazone 15mg+Metformin Hcl IP (SR)1000mg uncoated bilayered tablets	Not Mentioned	i. Anti-diabetic ii. Not Submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination could be appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/ 2mg/ 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	USV Ltd.	Glimepiride IP 1mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (SR) 1000mg uncoated bilayered tablets	It is indicated as once daily, as an adjuvant to diet and exercise, to lower blood glucose. It is indicated as second-line therapy with diet, exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type 2 diabetes.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy. In these patients, triple drug combination could be appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/ 2mg/ 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Windlas Biotech	Glimepiride IP 2mg+Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (SR) 1000mg tablets	Indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycaemic control in patients with type I diabetes.	i. Indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycaemic control in patients with type Iidiabetes ii. Not Approved	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy. In these patients, triple drug combination could be appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/ 2mg/ 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/1000mg/1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Windlas Biotech	Glimepiride IP 1mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (SR) 1000mg tablets	Indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycaemic control in patients with type I diabetes.	i. Indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycaemic control in patients with type Iidiabetes ii. Not Approved	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy. In this patient population, triple drug combination could be appropriate for enahancing the patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/ 2mg/ 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/1000mg/1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	Lupin Limited	Metformin HCl 1000mg+ Pioglitazone HCl 15mg+ Glimepiride 2mg tablet	As 3rd line treatment of type 2 diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control.	i. Same as Annexure-A ii. Not Submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns." The Subcommittee observed that: 1. As per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 2. As per the standard treatment guidelines for Type-2 Diabetes followed in India, patients not responding to diet, exercise, monotherapy (Metformin) or dual therapy (Sulfonylurea/ Biguanide) are treated with triple drug therapy. 3. There is a sufficiently large population of patients not responding to diet, exercise along with mono therapy and dual therapy, triple drug combination is appropriate for patient compliance in this chronic disease. 4. The DCGI has approved FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet for indication: "As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control" on 16.08.2005 with certain precautions to adress Pioglitazone associated safety concerns. 5. The FDC (Glimepiride IP 1mg/ 2mg/ 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg/ 15mg+ Metformin HCl IP (Immediate Release/ Sustained Release/ Extended Release) 1000mg/ 1000mg/ 1000mg tablets contains recommended and approved therapeutic dosage of each ingredient. 6. The Subcommittee concluded that the FDC has therapeutic value and has the potential to address the need of patients with type 2 diabetes not responding to diet, exercise, mono or dual therapy when the dose of individual drugs has been determined/ stabilised with single ingredient tablets. 7. However, this FDC can lead to risk of hypoglycaemia. There is no safety data pertaining to this FDC.
102	S.O. 806 (E)	Glimepiride 1mg/ 2mg/ 3mg+ Pioglitazone 15mg/ 15mg/ 15mg+ Metformin 1000mg/ 1000mg/ 1000mg	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation:** **The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 807(E)	glimepiride 1mg/ 2mg+ Pioglitazone 15mg/ 15mg + Metformin 850mg/ 850mg	Windlas Biotech	Glimepiride IP 2mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (SR) 850mg tablets	Indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycaemic control in patients with type I diabetes.	i. Glimepiride, Pioglitazone & Metformine Tablets are indicated once daily, as an adjunct to diet and exercise,to lower blood glucose. It is indicated as second line therapy when diet, exercise, and the single agents or dual therapy do not result in adequate glycaemic control in patients with type II diabetes ii. Not Approved	The Subcommittee noted that: 1. There are sufficient therapeutic options already available. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 807(E)	glimepiride 1mg/ 2mg+ Pioglitazone 15mg/ 15mg + Metformin 850mg/ 850mg	Windlas Biotech	Glimepiride IP 1mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+Metformin Hcl IP (SR) 850mg tablets	It is indicated as second line therapy when diet, exercise, single agents and dual combination therapy do not result in adequate glycemic control in patients with Type I diabetes As per pack insert: Glimepiride, Pioglitazone and Metformin Tablets are indicated once daily, as an adjuvant to diet and exercise, to lower blood glucose. It is in dicated as second-line therapy, when diet, exercise and the single agents or dual therapy do not result in adequate control in patients with type 2 diabetes.	i.Indication is same as annexure-A ii.Not submitted	The Subcommittee noted that: 1. There are sufficient therapeutic options already available. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 807(E)	glimepiride 1mg/ 2mg+ Pioglitazone 15mg/ 15mg + Metformin 850mg/ 850mg	Sun Pharma Industries	Glimepiride IP 1mg/ 2mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg/ 15mg+ Metformin Hcl IP (ER) 850mg/ 850mg uncoated bilayered tablets	The proposed FDC should not be used as first line therapy for diabetes. The proposed FDC is indicated as 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with drugs do not result in adequate glycemic control.	i. Indication same as Annexure A. ii. Not Submitted	The Subcommittee noted that: 1. There are sufficient therapeutic options already available. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 807(E)	glimepiride 1mg/ 2mg+ Pioglitazone 15mg/ 15mg + Metformin 850mg/ 850mg	Eris Life Sciences	Glimepiride IP 1mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (ER) 850mg uncoated bilayered tablets	As an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes who do not achieve glycemic control with diet and exercise alone. It is indicated as second line therapy when diet, exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type 2 diabetes	i. Indication same as Annexure A. ii. Not approved in any other country	The Subcommittee noted that: 1. There are sufficient therapeutic options already available. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 807(E)	glimepiride 1mg/ 2mg+ Pioglitazone 15mg/ 15mg + Metformin 850mg/ 850mg	Eris Life Sciences	Glimepiride IP 2mg+Pioglitazone HCl IP eq. to Pioglitazone 15mg+Metformin Hcl IP (ER) 850mg uncoated bilayered tablets	As an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes who do not achieve glycemic control with diet and exercise alone. It is indicated as second line therapy when diet, exercise and the single agents or dual therapy do not result in adequate glycemic control in patients with type 2 diabetes.	i. Indication same as Annexure A. ii. Not approved in any other country	The Subcommittee noted that: 1. There are sufficient therapeutic options already available. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no convincing scientific/ clinical evidence/ justification for the FDC.
103	S.O. 807(E)	glimepiride 1mg/ 2mg+ Pioglitazone 15mg/ 15mg + Metformin 850mg/ 850mg	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & Justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 808(E)	Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 2mg	Windlas biotech	Glimepiride 2mg + Pioglitazone HCl I.P. equivalent to Pioglitazone 7.5mg + Metformin HCl I.P. 850mg	Triglimestar-2 Tablets is used for Lower blood glucose in adults with type 2 diabetes mellitus (as per PI-Triglimestar-2 Tablets is used for the treatment of type 2 diabetes mellitus Maturity onset diabetes, Type 2 diabetes mellitus, polycystic ovary syndrome, Lower blood glucose in adults with type 2 diabetes mellitus and other conditions.)	i) Indication as per Annexure A ii) Not mentioned	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved by CDSCO for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control on 16.08.2005 The Subcommittee noted that similar FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under-"The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with 15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012."The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. 4. There are sufficient therapeutic options already available. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no sound convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 808(E)	Glimepiride 1 mg + Pioglitazone 7.5 + Metformin 850 mg L	Mankind Pharma	Glimepiride IP 2mg+ Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Metformin Hcl IP (SR) 850mg uncoated bilayered tablets	used for lower blood glucose in adults with type 2 diabetes mellitus, Type 2 diabetes mellitus.	I.for treatment of Type-2 diabetes mellitus, Maturity onset diabetes, polycystic ovary syndrome, lower blood glucose in adults with type 2 diabetes mellitus and other conditions. It may be used for purposes not listed in the medication guide. II.Not submitted	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved by CDSCO for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control on 16.08.2005 The Subcommittee noted that similar FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with 15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. 4. There are sufficient therapeutic options already available. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no sound convincing scientific/ clinical evidence/ justification for the FDC.
104	S.O. 808(E)	Glimepiride 1 mg + Pioglitazone 15 + Metformin 850 mg L	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 809(E)	Metformin 850mg+ Pioglitazone 7.5 mg+ Glimepiride 1mg	Mankind Pharma	Glimepiride IP 1mg+ Pioglitazone HCl IP eq. to Pioglitazone 7.5mg+ Metformin Hcl IP (SR) 850mg uncoated bilayered tablets	used for lower blood glucose in adults with type 2 diabetes mellitus, Type 2 diabetes mellitus.	i. for treatment of Type-2 diabetes mellitus, Maturity onset diabetes, polycystic ovary syndrome, lower blood glucose in adults with type 2 diabetes mellitus and other conditions. It may be used for purposes not listed in the medication guide. ii. None	The Subcommittee noted that FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin (500mg E.R) uncoated Tablet is approved by CDSCO for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control on 16.08.2005 The Subcommittee noted that similar FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with 15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. 4. There are sufficient therapeutic options already available. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no sound convincing scientific/ clinical evidence/ justification for the FDC.
105	S.O. 809(E)	Metformin 850mg+ Pioglitazone 7.5 mg+ Glimepiride 1mg	**Recommendation and grounds/ reasons for recommending prohibition/ restriction/ regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 810(E)	Metformin 500mg/ 500mg+ Gliclazide SR 30mg/ 60mg+ Pioglitazone 7.5mg/ 7.5mg	Inventia	Metformin HCl IP (SR) 500mg+ Gliclazide SR 60mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg uncoated bilayered tablet	As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control.	i. Should not be used as first line therapy for diabetes mellitus. Indicated in the treatment of type 2 diabetes mellitus when diet, exercise and the single agents like sulfonylurea or Metformin as well as second line therapy with two drugs do not result in adequate glycemic control ii. Not Approved	The Subcommittee noted that FDC of Metformin SR 500mg/500mg + Gliclazide SR 60mg/ 30mg + Pioglitazone 15mg/ 15mg tablets is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control on 28.05.2010. The Subcommittee noted that similar FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Subcommittee noted that Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the FDC of Metformin 500mg/ 500mg + Gliclazide SR 30mg/ 60mg + Pioglitazone 7.5mg/ 7.5mg, as inappropriate due to lack of any therapeutic justification. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 810(E)	Metformin 500mg/ 500mg+ Gliclazide SR 30mg/60mg+ Pioglitazone 7.5mg/7.5mg	Inventia	Metformin HCl IP (SR) 500mg+ Gliclazide SR 30mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg uncoated bilayered tablet	As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control.	i. Should not be used as first line therapy for diabetes mellitus. Indicated in the treatment of type 2 diabetes mellitus when diet, exercise and the single agents like sulfonylurea or Metformin as well as second line therapy with two drugs do not result in adequate glycemic control ii. Not Approved	The Subcommittee noted that FDC of Metformin SR 500mg/500mg + Gliclazide SR 60mg/30mg + Pioglitazone 15mg/15mg tablets is approved for the indication: As 3rd line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control on 28.05.2010. The Subcommittee noted that similar FDC was discussed earlier by previous "10 expert Committee" on 27.08.14 as under- "The usual dose of Pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of Pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of Pioglitazone with15 mg of Pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of Pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012." The Subcommittee concurred with the recommendation of "10 expert committee". The Subcommittee perused recent publications and concluded that: 1. The evidence for efficacy of 7.5mg Pioglitazone is not sufficient. 2. Further, Subcommittee noted that Pioglitazone 7.5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. The Subcommittee considered the FDC of Metformin 500mg/ 500mg + Gliclazide SR 30mg/ 60mg + Pioglitazone 7.5mg/7.5mg, as inappropriate due to lack of any therapeutic justification. There is no convincing scientific/ clinical evidence/ justification for the FDC.
106	S.O. 810(E)	Metformin 500mg/ 500mg+ Gliclazide SR 30mg/ 60mg+ Pioglitazone 7.5mg/ 7.5mg	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 811(E)	Voglibose + Pioglitazone + Metformin	-	-	-	-	1. Pharmacokinetic mismatch: Voglibose is to be given three times a day whereas Pioglitazone is given once or twice daily. There is no sound scientific/clinical evidence/ justification for the FDC.
107	S.O. 811(E)	Voglibose + Pioglitazone + Metformin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AfDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 812(E)	Metformin + Bromocriptine	-	-	-	-	1. Pharmacokinetic mismatch: Metformin is given 2-3 times a day whereas Bromocriptine is given once daily. 2. With this FDC, dose titration becomes difficult in case of adverse reactions observed with Bromocriptine. There is no sound scientific/ clinical evidence/ justification for the FDC.
108	S.O. 812(E)	Metformin + Bromocriptine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 813(E)	Metformin+ Glimepiride+ Methylcobalamin	Acon Formulations	Metformin HCl IP 500mg (As a SR form)+ Glimepiride IP 1mg+ Methylcobalamin JP 750mcg uncoated bilayered tablet	To be used for the treatment of Type-II diabetes	i. Submitted ii. Not submitted	The Subcommittee noted the comments of Kokate committee for this FDC as under: "Pharmacodynamically irrelevant- 1. No published literature supporting the superior efficacy of combination of three drugs. 2. Use of Methylcobalamine as prophylaxis in FDC is not documented." The Subcommittee concurred with the above. The Subcommittee also noted that: 1. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
109	S.O. 813(E)	Metformin + Glimepiride + Methylcobalamin	**Recommendation and grounds/ reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 814(E)	Pioglitazone 30 mg+ Metformin 500mg	Inventia	Pioglitazone HCl IP eq. To Pioglitazone 30mg+ Metformin HCl IP 500mg (SR) uncoated bilayered tablet	Second line therapy of Type II diabetes mellitus when diet, exercise and the single agent do not result in adequate glycaemic control.	i. Monotherapy: As adjunct to diet and exercise to improve glycaemic control in patients with Type II diabetes.Concomitantly: withsulphonyl urea or insulin to improve glycemic control in adults ii. YES (AcCTOPLUS MET XR, Approved by USFDA)	The Subcommittee noted that FDC of Pioglitazone Hydrochloride Eq. to Pioglitazone 15mg/30mg + Metformin HCl IP 500mg (ER) tablets is approved for indication: Second line therapy on type-II diabetes on 25.02.2005 by CDSCO. The Subcommittee noted that: 1. The dose titration to increase the dose of Metformin will lead to inadvertent overdose of Pioglitazone with FDC of Pioglitazone 30mg+ Metformin 500mg. This involves risk to the patient population. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 814(E)	Pioglitazone 30 mg+ Metformin 500mg	Lupin	Pioglitazone HCl 30mg+ Metformin HCl 500mg uncoated bilayered tablet	As second line treatment of Type II diabetes mellitus when diet, exercise and single agents don ot result in adequate glycaemic control.	i. Indicated as an adjunct to diet and exercise as second line therapy to improve glycemic control in adults with Type II diabetes mellitus who are already treated with Pioglitazone and Metformin or who have inadequate glycaemic control on single drug. ii. Not Approved	The Subcommittee noted that FDC of Pioglitazone Hydrochloride Eq. to Pioglitazone 15mg/30mg + Metformin HCl IP 500mg (ER) tablets is approved for indication: Second line therapy on type-II diabetes on 25.02.2005 by CDSCO. The Subcommittee noted that: 1. The dose titration to increase the dose of Metformin will lead to inadvertent overdose of Pioglitazone with FDC of Pioglitazone 30mg + Metformin 500mg. This involves risk to the patient population. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 814(E)	Pioglitazone 30 mg+ Metformin 500mg	Eris Lifesciences	Pioglitazone HCl IP eq. To Pioglitazone 30mg+ Metformin HCl IP 500mg (SR) uncoated bilayered tablet	Used as an adjuvant to diet and exercise to improve glycaemic control in patients with type II diabetes who donot achieve glycemic control with diet and exercise alone. It is indicated as second line therapy when diet,exercise and the single agents or dual therapy do not result in adequate glycaemic control in patients with Type II diabetes.	i. Indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type-2 diabetes mellitus in multiple clinical settings. ii.NotApproved	The Subcommittee noted that FDC of Pioglitazone Hydrochloride Eq. to Pioglitazone 15mg/30mg + Metformin HCl IP 500mg (ER) tablets is approved for indication: Second line therapy on type-II diabetes on 25.02.2005 by CDSCO. The Subcommittee noted that: 1. The dose titration to increase the dose of Metformin will lead to inadvertent overdose of Pioglitazone with FDC of Pioglitazone 30mg + Metformin 500mg. This involves risk to the patient population. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 814(E)	Pioglitazone 30 mg+ Metformin 500mg	Mankind Pharma	Pioglitazone HCl IP eq. to Pioglitazone 30mg+Metformin Hcl IP (SR) 500mg film coated tablets	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	i. Indication same as Annexure A. ii. Not approved	The Subcommittee noted that FDC of Pioglitazone Hydrochloride Eq. to Pioglitazone 15mg/30mg + Metformin HCl IP 500mg (ER) tablets is approved for indication: Second line therapy on type-II diabetes on 25.02.2005 by CDSCO. The Subcommittee noted that: 1. The dose titration to increase the dose of Metformin will lead to inadvertent overdose of Pioglitazone with FDC of Pioglitazone 30mg + Metformin 500mg. This involves risk to the patient population. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 814(E)	Pioglitazone 30 mg+ Metformin 500mg	Sun Pharma Industries	Pioglitazone HCl IP eq. to Pioglitazone 30mg+ Metformin Hcl IP (ER) 500mg film coated tablets	The proposed FDC should not be used as first line of therapy for diabetes. The proposed FDC is indicated as second line treatment of type-2 diabetes mellitus adult patients. Particularly overweight patients, who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral Metformin alone	i. Indication same as Annexure A. ii. Not submitted	The Subcommittee noted that FDC of Pioglitazone Hydrochloride Eq. to Pioglitazone 15mg/ 30mg + Metformin HCl IP 500mg (ER) tablets is approved for indication: Second line therapy on type-II diabetes on 25.02.2005 by CDSCO. The Subcommittee noted that: 1. The dose titration to increase the dose of Metformin will lead to inadvertent overdose of Pioglitazone with FDC of Pioglitazone 30mg + Metformin 500mg. This involves risk to the patient population. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 814(E)	Pioglitazone 30 mg+ Metformin 500mg	USV Ltd.,	Pioglitazone HCl IP eq. to Pioglitazone 30mg+ Metformin Hcl IP (SR) 500mg film coated tablets	Used in Management of Type II diabetes. As adjunct to diet and exercise to improve glycaemic control in patients with Type II diabetes who are already treated with combination of Pioglitazone and Metformin or whose diabetes is not adequately controlled with Metformin alone, or for those patients who have initially responded to Pioglitazone alone and require additional glycaemic control.	i. Indication same as Annexure A. ii. Available in countries like Philippines,Mexico and Dominican republic.	The Subcommittee noted that FDC of Pioglitazone Hydrochloride Eq. to Pioglitazone 15mg/ 30mg+ Metformin HCl IP 500mg (ER) tablets is approved for indication: Second line therapy on type-II diabetes on 25.02.2005 by CDSCO. The Subcommittee noted that: 1. The dose titration to increase the dose of Metformin will lead to inadvertent overdose of Pioglitazone with FDC of Pioglitazone 30mg + Metformin 500mg. This involves risk to the patient population. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 814(E)	Pioglitazone 30 mg+ Metformin 500mg	Skymap Pharmaceutical	Pioglitazone 30mg+ Metformin 500mg film coated tablet	Anti-Diabetic	i. Not Submitted ii. Not Submitted	The Subcommittee noted that FDC of Pioglitazone Hydrochloride Eq. to Pioglitazone 15mg/30mg + Metformin HCl IP 500mg (ER) tablets is approved for indication: Second line therapy on type-II diabetes on 25.02.2005 by CDSCO. The Subcommittee noted that: 1. The dose titration to increase the dose of Metformin will lead to inadvertent overdose of Pioglitazone with FDC of Pioglitazone 30mg + Metformin 500mg. This involves risk to the patient population. There is no convincing scientific/ clinical evidence/ justification for the FDC.
110	S.O. 814(E)	Pioglitazone 30 mg+ Metformin 500mg	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 815(E)	Glimepiride + Pioglitazone + Metformin	Mankind Pharma	Glimepiride IP 4mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (ER) 500mg uncoated bilayered tablets	This is used for Lower blood glucose in adults with type 2 diabetes mellitus, Type 2 diabetes mellitus,	i.Indication same as annexuer-A ii.Not submitted	The Subcommittee was informed by CDSCO that vide reference to F.No 04/01/2013-DC (Misc 13- PSC) dated 14.03.2016 it has been informed to the Ministry that "During preparation of list, FDC of Glimepiride + Pioglitazone + Metformin was typed inadvertently at S.No 113 because of some confusion at various strengths of this product are declared as irrational but product as such is not declared as irrational. More so, this product in some strengths is already approved by DCG(I) in 2005. Therefore, it may be considered as inadvertent entry and may be omitted from the list and suitable notification may be issued in this regard." The Subcommittee noted that at S.O. 815, the quantity of ingredients of Glimepiride, Pioglitazone and Metformin is not specifically mentioned. The Subcommittee noted that the DCG(I) has already approved the FDC containing Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500mg E.R) uncoated Tablet. In view of above, the Subcommittee recommended that FDC of Glimepiride + Pioglitazone + Metformin should be restricted under section 26A of the D&C act as under: 1. FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin 500mg (Immediate Release/ Sustained Release/ Extended Release) Tablet for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strengths is 'rational' for the defined patient population. Any other strength of FDC of Glimepiride +Pioglitazone +Metformin except above mentioned strengths is not recommended.
	S.O. 815(E)	Glimepiride + Pioglitazone + Metformin	Psychotropics India Ltd.	Glimepiride IP 4mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (ER) 500mg uncoated bilayered tablets	Not submitted	Not submitted	The Subcommittee was informed by CDSCO that vide reference to F.No 04/01/2013-DC (Misc 13- PSC) dated 14.03.2016 it has been informed to the Ministry that "During preparation of list, FDC of Glimepiride + Pioglitazone + Metformin was typed inadvertently at S.No 113 because of some confusion at various strengths of this product are declared as irrational but product as such is not declared as irrational. More so, this product in some strengths is already approved by DCG(I) in 2005. Therefore, it may be considered as inadvertent entry and may be omitted from the list and suitable notification may be issued in this regard." The Subcommittee noted that at S.O. 815, the quantity of ingredients of Glimepiride, Pioglitazone and Metformin is not specifically mentioned. The Subcommittee noted that the DCG(I) has already approved the FDC containing Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500mg E.R) uncoated Tablet. In view of above, the Subcommittee recommended that FDC of Glimepiride + Pioglitazone + Metformin should be restricted under section 26A of the D&C act as under: 1. FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin 500mg (Immediate Release/ Sustained Release/ Extended Release) Tablet for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strengths is 'rational' for the defined patient population. Any other strength of FDC of Glimepiride +Pioglitazone +Metformin except above mentioned strengths is not recommended.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 815(E)	Glimepiride + Pioglitazone + Metformin	Mankind Pharma	Glimepiride IP 5mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (SR) 500mg uncoated bilayered tablets	Glucomust PM Tablet is used for Treatment of type 2 diabetes mellitus, Maturity onset diabetes, Type 2 diabetes mellitus, polycystic ovary syndrome, Lower blood glucose in adults with type 2 diabetes mellitus and other conditions.	i.Glucomust-PM Tablet is used in the treatment of type 2 diabetes. ii.Not submitted	The Subcommittee was informed by CDSCO that vide reference to F.No 04/01/2013-DC (Misc 13- PSC) dated 14.03.2016 it has been informed to the Ministry that "During preparation of list, FDC of Glimepiride + Pioglitazone + Metformin was typed inadvertently at S.No 113 because of some confusion at various strengths of this product are declared as irrational but product as such is not declared as irrational. More so, this product in some strengths is already approved by DCG(I) in 2005. Therefore, it may be considered as inadvertent entry and may be omitted from the list and suitable notification may be issued in this regard." The Subcommittee noted that at S.O. 815, the quantity of ingredients of Glimepiride, Pioglitazone and Metformin is not specifically mentioned. The Subcommittee noted that the DCG(I) has already approved the FDC containing Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500mg E.R) uncoated Tablet. In view of above, the Subcommittee recommended that FDC of Glimepiride + Pioglitazone + Metformin should be restricted under section 26A of the D&C act as under: 1. FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin 500mg (Immediate Release/ Sustained Release/ Extended Release) Tablet for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strengths is 'rational' for the defined patient population. Any other strength of FDC of Glimepiride + Pioglitazone +Metformin except above mentioned strengths is not recommended.
	S.O. 815(E)	Glimepiride + Pioglitazone + Metformin	Mefro Organic	Glimepiride 1mg+ Pioglitazone HCl 15mg+ Metformin HCl 500mg tablet	Not submitted	i.Not submitted ii.Not submitted	The Subcommittee was informed by CDSCO that vide reference to F.No 04/01/2013-DC (Misc 13- PSC) dated 14.03.2016 it has been informed to the Ministry that "During preparation of list, FDC of Glimepiride + Pioglitazone + Metformin was typed inadvertently at S.No 113 because of some confusion at various strengths of this product are declared as irrational but product as such is not declared as irrational. More so, this product in some strengths is already approved by DCG(I) in 2005. Therefore, it may be considered as inadvertent entry and may be omitted from the list and suitable notification may be issued in this regard." The Subcommittee noted that at S.O. 815, the quantity of ingredients of Glimepiride, Pioglitazone and Metformin is not specifically mentioned. The Subcommittee noted that the DCG(I) has already approved the FDC containing Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500mg E.R) uncoated Tablet. In view of above, the Subcommittee recommended that FDC of Glimepiride + Pioglitazone + Metformin should be restricted under section 26A of the D&C act as under: 1. FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin 500mg (Immediate Release/ Sustained Release/ Extended Release) Tablet for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strengths is 'rational' for the defined patient population. Any other strength of FDC of Glimepiride +Pioglitazone +Metformin except above mentioned strengths is not recommended.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 815(E)	Glimepiride + Pioglitazone + Metformin	Jubilant Life Sciences	Glimepiride 1mg/ 2mg+ Pioglitazone HCl 15mg+ Metformin HCl 500mg tablet	antidiabetic drug. (Package insert indication not clearly visible)	i.indication same as annexuer-A ii.Not submitted	The Subcommittee was informed by CDSCO that vide reference to F.No 04/01/2013-DC (Misc 13- PSC) dated 14.03.2016 it has been informed to the Ministry that "During preparation of list, FDC of Glimepiride + Pioglitazone + Metformin was typed inadvertently at S.No 113 because of some confusion at various strengths of this product are declared as irrational but product as such is not declared as irrational. More so, this product in some strengths is already approved by DCG(I) in 2005. Therefore, it may be considered as inadvertent entry and may be omitted from the list and suitable notification may be issued in this regard." The Subcommittee noted that at S.O. 815, the quantity of ingredients of Glimepiride, Pioglitazone and Metformin is not specifically mentioned. The Subcommittee noted that the DCG(I) has already approved the FDC containing Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500mg E.R) uncoated Tablet. In view of above, the Subcommittee recommended that FDC of Glimepiride + Pioglitazone + Metformin should be restricted under section 26A of the D&C act as under: 1. FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin 500mg (Immediate Release/ Sustained Release/ Extended Release) Tablet for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strengths is 'rational' for the defined patient population. Any other strength of FDC of Glimepiride +Pioglitazone +Metformin except above mentioned strengths is not recommended.
	S.O. 815(E)	Glimepiride + Pioglitazone + Metformin	Mefro Organic	Glimepiride 2mg+ Pioglitazone HCl 15mg+ Metformin HCl 500mg tablet	Not submitted	i.Not submitted ii.Not submitted	The Subcommittee was informed by CDSCO that vide reference to F.No 04/01/2013-DC (Misc 13- PSC) dated 14.03.2016 it has been informed to the Ministry that "During preparation of list, FDC of Glimepiride + Pioglitazone + Metformin was typed inadvertently at S.No 113 because of some confusion at various strengths of this product are declared as irrational but product as such is not declared as irrational. More so, this product in some strengths is already approved by DCG(I) in 2005. Therefore, it may be considered as inadvertent entry and may be omitted from the list and suitable notification may be issued in this regard." The Subcommittee noted that at S.O. 815, the quantity of ingredients of Glimepiride, Pioglitazone and Metformin is not specifically mentioned. The Subcommittee noted that the DCG(I) has already approved the FDC containing Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500mg E.R) uncoated Tablet. In view of above, the Subcommittee recommended that FDC of Glimepiride + Pioglitazone + Metformin should be restricted under section 26A of the D&C act as under: 1. FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin 500mg (Immediate Release/ Sustained Release/ Extended Release) Tablet for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strengths is 'rational' for the defined patient population. Any other strength of FDC of Glimepiride +Pioglitazone +Metformin except above mentioned strengths is not recommended.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 815(E)	Glimepiride + Pioglitazone + Metformin	Psychotropics India Ltd.	Glimepiride 2mg+ Pioglitazone HCl 15mg+ Metformin HCl 500mg tablet	Not Submitted	i.Not Submitted ii.Not submitted	The Subcommittee was informed by CDSCO that vide reference to F.No 04/01/2013-DC (Misc 13- PSC) dated 14.03.2016 it has been informed to the Ministry that "During preparation of list, FDC of Glimepiride + Pioglitazone + Metformin was typed inadvertently at S.No 113 because of some confusion at various strengths of this product are declared as irrational but product as such is not declared as irrational. More so, this product in some strengths is already approved by DCG(I) in 2005. Therefore, it may be considered as inadvertent entry and may be omitted from the list and suitable notification may be issued in this regard." The Subcommittee noted that at S.O. 815, the quantity of ingredients of Glimepiride, Pioglitazone and Metformin is not specifically mentioned. The Subcommittee noted that the DCG(I) has already approved the FDC containing Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500mg E.R) uncoated Tablet. In view of above, the Subcommittee recommended that FDC of Glimepiride + Pioglitazone + Metformin should be restricted under section 26A of the D&C act as under: 1. FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin 500mg (Immediate Release/ Sustained Release/ Extended Release) Tablet for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strengths is 'rational' for the defined patient population. Any other strength of FDC of Glimepiride +Pioglitazone +Metformin except above mentioned strengths is not recommended.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 815(E)	Glimepiride + Pioglitazone + Metformin	Psychotropics India Ltd.	Glimepiride 1mg+ Pioglitazone HCl 15mg+ Metformin HCl 500mg tablet	Not Submitted	i.Not Submitted ii.Not submitted	The Subcommittee was informed by CDSCO that vide reference to F.No 04/01/2013-DC (Misc 13- PSC) dated 14.03.2016 it has been informed to the Ministry that "During preparation of list, FDC of Glimepiride + Pioglitazone + Metformin was typed inadvertently at S.No 113 because of some confusion at various strengths of this product are declared as irrational but product as such is not declared as irrational. More so, this product in some strengths is already approved by DCG(I) in 2005. Therefore, it may be considered as inadvertent entry and may be omitted from the list and suitable notification may be issued in this regard." The Subcommittee noted that at S.O. 815, the quantity of ingredients of Glimepiride, Pioglitazone and Metformin is not specifically mentioned. The Subcommittee noted that the DCG(I) has already approved the FDC containing Glimepiride (1mg/2mg) + Pioglitazone (15mg) + Metformin (500mg E.R) uncoated Tablet. In view of above, the Subcommittee recommended that FDC of Glimepiride + Pioglitazone + Metformin should be restricted under section 26A of the D&C act as under: 1. FDC of Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin 500mg (Immediate Release/ Sustained Release/ Extended Release) Tablet for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strengths is 'rational' for the defined patient population. Any other strength of FDC of Glimepiride +Pioglitazone +Metformin except above mentioned strengths is not recommended.
111	S.O. 815(E)	Glimepiride + Pioglitazone + Metformin	**In the larger public interest, the Subcommittee is of the opinion that S.O. 815 may be amended as under. FDC of Glimepiride + Pioglitazone + Metformin may be restricted under section 26A for the following strengths:** **1. Glimepiride (1mg/2mg) + Pioglitazone (15mg)+ Metformin 500mg (Immediate Release/ Sustained Release/ Extended Release) Tablet** **for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strengths is 'rational' for the defined patient population.** **Further, the label and all the promotional literature including the package insert shall mention the precautions for individual drugs.** **Any other strength of FDC of Glimepiride +Pioglitazone +Metformin except above mentioned strengths is not recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 816(E)	Glipizide 2.5mg+ Metformin 400mg	-	-	-	-	The Subcommittee noted that this FDC was discussed earlier by previous "10 expert Committee on 27.08.14 as under- " The firm could not present any scientific data with respect to the proposed strength of FDC. The committee opined that the proposed strength is not going to add any benefit to the patient over the already approved strengths of the FDC. Hence the committee did not recommend." The Subcommittee concurred with above. Also: 1. Dosage of Glipizide and Metformin are sub-therapeutic and not justified. It's use can result in uncontrolled diabetes and risk associated with it. There is no sound scientific/ clinical evidence/ justification for the FDC.
112	S.O. 816(E)	Glipizide 2.5mg+ Metformin 400mg	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 817(E)	Pioglitazone 15mg+ Metformin 850 mg	-	-	-	-	The Subcommittee noted that: 1. There are sufficient therapeutic options already available. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing and side effects or under-dosing and uncontrolled diabetes. There is no sound scientific/ clinical evidence/ justification for the FDC.
113	S.O. 817(E)	Pioglitazone 15mg+ Metformin 850 mg	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 818(E)	Metformin ER+ Gliclazide MR+ Voglibose	-	-	-	-	The Subcommittee noted that this FDC was discussed earlier by "10 expert Committee" on 27.08.14 and comments are as under- "The firm could not present any scientific data with respect to this FDC. The dosing of voglibose is incompatible with the dosing schedule of Metformin ER and gliclazide SR. Hence the committee did not recommend." The Subcommittee concurred with above recommendations of "10 expert committee" as there is: 1. Pharamacokinetic mismatch in this FDC: Voglibose is given three times a day whereas Metformin ER and Gliclazide MR are given once/twice a day. There is no sound scientific/ clinical evidence/ justification for the FDC.
114	S.O. 818(E)	Metformin ER+ Gliclazide MR+ Voglibose	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 819(E)	Chromium Polynicotinate+ Metformin Hydrochloride	-	-	-	-	1. The current literature is inconclusive about the benefits of Chromium in combination with Metformin. 2. None of the guidelines mention Chromium as first, second or third line agent in treatment of diabetes either alone or in combination with other recommended anti-diabetic agents. There is no sound scientific/ clinical evidence/ justification for the FDC.
115	S.O. 819(E)	Chromium Polynicotinate+ Metformin Hydrochloride	Recommendation and grounds/ reasons for recommending prohibition/ restriction/ regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of iogredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 820(E)	Metformin Hydrochlopride + Gliclazide + Pioglitazone + Chromium Polynicotinate	-	-	-	-	1. The current literature is inconclusive about the benefits of Chromium in combination with Metformin. 2. None of the guidelines mention Chromium as first, second or third line agent in treatment of diabetes either alone or in combination with other recommended anti-diabetic agents. There is no sound scientific/ clinical evidence/ justification for the FDC.
116	S.O. 820(E)	Metformin Hydrochlopride + Gliclazide + Pioglitazone + Chromium Polynicotinate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 821(E)	Metformin + Gliclazide + Chromium Polynicotinate	-	-	-	-	1. The current literature is inconclusive about the benefits of Chromium in combination with Metformin. 2. None of the guidelines mention Chromium as first, second or third line agent in treatment of diabetes either alone or in combination with other recommended anti-diabetic agents. There is no sound scientific/ clinical evidence/ justification for the FDC.
117	S.O. 821(E)	Metformin + Gliclazide + Chromium Polynicotinate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 822(E)	Glibenclamide + Metformin (SR)+ Pioglitazone	Lupin	Glibenclamide 5mg + Metformin 500mg+ Pioglitazone 15mg uncoated bilayered tablet	As 3rd line treatment of Type II diabetes mellitus who diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control.	i) Same as Annexure A ii) Not submitted	The Subcommittee noted that S.O. 822 i.e. FDC of Glibenclamide + Metformin (SR) + Pioglitazone does not mention the strength of each ingredient. However, it mentions Metformin as Sustained Release (SR). The Subcommittee also noted that FDC of Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg film coated tablets is already approved by CDSCO on 23.02.2009 for the following indication: "As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control". Further, the Subcommittee observed that: 1. As per the standard treatment guidelines (ADA & AACE Guidelines) followed in India, patients not responding to diet, exercise, monotherapy (Metformin), dual therapy (Sulfonylurea/ Biguanide), triple drug therapy can be recommended . 2. There is a sufficiently large population of patients not responding to first line and second line therapy, and hence requiring third line treatment 3. Further, the Subcommittee noted that as per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 4. However, this S.O. 822 does not mention the strengths of individual ingredients. Individual ingredients have their own maximum permissible dosage. Hence, strength of individual ingredients should be mentioned. Hence, the triple drug combination of FDC of "Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg" which is already approved by DCG(I) was found to be appropriate for patient compliance for this chronic disease. Accordingly, apart from the already DCGI approved FDC of "Glibenclamide 5mg + Metformin 500mg + Pioglitazone 15 mg", the S.O. 822 may be amended as under: FDC of Glibenclamide + Metformin (SR) + Pioglitazone may be restricted under Section 26A of the D&C act for the following strength: Glibenclamide 5mg + Metformin 500mg (SR) + Pioglitazone 15mg for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target".

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 822(E)	Glibenclamide + Metformin (SR)+ Pioglitazone	USV	Glibenclamide IP 5mg+ Metformin HCl IP 500mg (SR)+ Pioglitazone HCl IP eq. To Pioglitazone 15mg uncoated bilayered tablet	As an adjunct to diet control and exercise to improve glycemic control in patient with type 2 diabetes whose diabetes is not adequately controlled in spite of being treated with any of 2 anti-diabetic agents present in Triglycomet (proposed FDC).	i) Same as Annexure A ii) Not submitted	The Subcommittee noted that S.O. 822 i.e. FDC of Glibenclamide + Metformin (SR) + Pioglitazone does not mention the strength of each ingredient. However, it mentions Metformin as Sustained Release (SR). The Subcommittee also noted that FDC of Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg film coated tablets is already approved by CDSCO on 23.02.2009 for the following indication: "As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control". Further, the Subcommittee observed that: 1. As per the standard treatment guidelines (ADA & AACE Guidelines) followed in India, patients not responding to diet, exercise, monotherapy (Metformin), dual therapy (Sulfonylurea/ Biguanide), triple drug therapy can be recommended . 2. There is a sufficiently large population of patients not responding to first line and second line therapy, and hence requiring third line treatment 3. Further, the Subcommittee noted that as per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 4. However, this S.O. 822 does not mention the strengths of individual ingredients. Individual ingredients have their own maximum permissible dosage. Hence, strength of individual ingredients should be mentioned. Hence, the triple drug combination of FDC of "Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg" which is already approved by DCG(I) was found to be appropriate for patient compliance for this chronic disease. Hence, the Subcommittee is of the opinion that in the larger public interest, the FDC {Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg (SR)} need not be prohibited but needs to be Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target". Accordingly, apart from the already DCGI approved FDC of "Glibenclamide 5mg + Metformin 500mg + Pioglitazone 15 mg", the S.O. 822 may be amended as under: FDC of Glibenclamide + Metformin (SR) + Pioglitazone may be prohibited under Section 26A of the D&C act except for the following strength: Glibenclamide 5mg + Metformin 500mg (SR) + Pioglitazone 15mg Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target".

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 822(E)	Glibenclamide + Metformin (SR)+ Pioglitazone	Micro	Glibenclamide IP 5mg+ Metformin HCl IP 500mg (SR)+ Pioglitazone HCl IP eq. To Pioglitazone 15mg uncoated bilayered tablet	As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control.	i) Same as Annexure A ii) Not submitted	The Subcommittee noted that S.O. 822 i.e. FDC of Glibenclamide + Metformin (SR) + Pioglitazone does not mention the strength of each ingredient. However, it mentions Metformin as Sustained Release (SR). The Subcommittee also noted that FDC of Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg film coated tablets is already approved by CDSCO on 23.02.2009 for the following indication: "As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control". Further, the Subcommittee observed that: 1. As per the standard treatment guidelines (ADA & AACE Guidelines) followed in India, patients not responding to diet, exercise, monotherapy (Metformin), dual therapy (Sulfonylurea/ Biguanide), triple drug therapy can be recommended . 2. There is a sufficiently large population of patients not responding to first line and second line therapy, and hence requiring third line treatment 3. Further, the Subcommittee noted that as per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 4. However, this S.O. 822 does not mention the strengths of individual ingredients. Individual ingredients have their own maximum permissible dosage. Hence, strength of individual ingredients should be mentioned. Hence, the triple drug combination of FDC of "Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg" which is already approved by DCG(I) was found to be appropriate for patient compliance for this chronic disease. Hence, the Subcommittee is of the opinion that in the larger public interest, the FDC {Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg (SR)} need not be prohibited but needs to be Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target". Accordingly, apart from the already DCGI approved FDC of "Glibenclamide 5mg + Metformin 500mg + Pioglitazone 15 mg", the S.O. 822 may be amended as under: FDC of Glibenclamide + Metformin (SR) + Pioglitazone may be prohibited under Section 26A of the D&C act except for the following strength: Glibenclamide 5mg + Metformin 500mg (SR) + Pioglitazone 15mg Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target".

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 822(E)	Glibenclamide + Metformin (SR)+ Pioglitazone	Sun	Glibenclamide IP 5mg+ Metformin HCl IP 500mg+ Pioglitazone HCl IP eq. To Pioglitazone 7.5mg film coated tablet	The proposed FDC should not be used first line therapy for diabetes. It is indicated as 3rd line therapy of type-II diabetes mellitus when, diet, exercise and the single agent and second line therapy with drugs do not results in adequate glycemic control	i) Same as Annexure A ii) Not submitted	The Subcommittee noted that S.O. 822 i.e. FDC of Glibenclamide + Metformin (SR) + Pioglitazone does not mention the strength of each ingredient. However, it mentions Metformin as Sustained Release (SR). The Subcommittee also noted that FDC of Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg film coated tablets is already approved by CDSCO on 23.02.2009 for the following indication: "As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control". Further, the Subcommittee observed that: 1. As per the standard treatment guidelines (ADA & AACE Guidelines) followed in India, patients not responding to diet, exercise, monotherapy (Metformin), dual therapy (Sulfonylurea/ Biguanide), triple drug therapy can be recommended . 2. There is a sufficiently large population of patients not responding to first line and second line therapy, and hence requiring third line treatment 3. Further, the Subcommittee noted that as per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 4. However, this S.O. 822 does not mention the strengths of individual ingredients. Individual ingredients have their own maximum permissible dosage. Hence, strength of individual ingredients should be mentioned. Hence, the triple drug combination of FDC of "Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg" which is already approved by DCG(I) was found to be appropriate for patient compliance for this chronic disease. Hence, the Subcommittee is of the opinion that in the larger public interest, the FDC {Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg (SR)} need not be prohibited but needs to be Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target". Accordingly, apart from the already DCGI approved FDC of "Glibenclamide 5mg + Metformin 500mg + Pioglitazone 15 mg", the S.O. 822 may be amended as under: FDC of Glibenclamide + Metformin (SR) + Pioglitazone may be prohibited under Section 26A of the D&C act except for the following strength: Glibenclamide 5mg + Metformin 500mg (SR) + Pioglitazone 15mg Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target".

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 822(E)	Glibenclamide + Metformin (SR)+ Pioglitazone	Tristar Formulations	Glibenclamide IP 5mg+Metformin HCL IP (SR) 500mg+Pioglitazone HCL IP eq. to Pioglitazone 15mg uncoated bilayered	Will be submitted in due course As per pack insert: As third line treatment of diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control	i) Same as Annexure A ii) Not submitted	The Subcommittee noted that S.O. 822 i.e. FDC of Glibenclamide + Metformin (SR) + Pioglitazone does not mention the strength of each ingredient. However, it mentions Metformin as Sustained Release (SR). The Subcommittee also noted that FDC of Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg film coated tablets is already approved by CDSCO on 23.02.2009 for the following indication: "As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control". Further, the Subcommittee observed that: 1. As per the standard treatment guidelines (ADA & AACE Guidelines) followed in India, patients not responding to diet, exercise, monotherapy (Metformin), dual therapy (Sulfonylurea/ Biguanide), triple drug therapy can be recommended . 2. There is a sufficiently large population of patients not responding to first line and second line therapy, and hence requiring third line treatment 3. Further, the Subcommittee noted that as per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 4. However, this S.O. 822 does not mention the strengths of individual ingredients. Individual ingredients have their own maximum permissible dosage. Hence, strength of individual ingredients should be mentioned. Hence, the triple drug combination of FDC of "Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg" which is already approved by DCG(I) was found to be appropriate for patient compliance for this chronic disease. Hence, the Subcommittee is of the opinion that in the larger public interest, the FDC {Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg (SR)} need not be prohibited but needs to be Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target". Accordingly, apart from the already DCGI approved FDC of "Glibenclamide 5mg + Metformin 500mg + Pioglitazone 15 mg", the S.O. 822 may be amended as under: FDC of Glibenclamide + Metformin (SR) + Pioglitazone may be prohibited under Section 26A of the D&C act except for the following strength: Glibenclamide 5mg + Metformin 500mg (SR) + Pioglitazone 15mg Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target".

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 822(E)	Glibenclamide + Metformin (SR)+ Pioglitazone	GKM New Pharma	Glibenclamide IP 5mg+Metformin HCL IP (SR) 500mg+Pioglitazone HCL IP eq. to Pioglitazone 15mg uncoated bilayered	As 3rd line treatment of typeII diabetes mellitus when diet,exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control. In Pack insert- Pioglitazone should not be used as first line therapy for diabetes. This FDC is indicated as an adjunct to diet and exercise to improve glycemic control in adults with glibenclimide and metformin or pioglitazone and metformin. Management of type-2 diabetes should also include nutritional counselling,weight reduction as needed and exercise.These efforts are important not only in the primary treatment of type-2 diabetes.but also to maintain the efficacy of drug therapy.Prior to intiation or escalation of oral antidiabetic therapy in patients with type-2 diabetes mellitus, secondary causes of poor glycemic control e.g.infection,should be investigated and treated.	i) Same as Annexure A ii) Not submitted	The Subcommittee noted that S.O. 822 i.e. FDC of Glibenclamide + Metformin (SR) + Pioglitazone does not mention the strength of each ingredient. However, it mentions Metformin as Sustained Release (SR). The Subcommittee also noted that FDC of Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg film coated tablets is already approved by CDSCO on 23.02.2009 for the following indication: "As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control". Further, the Subcommittee observed that: 1. As per the standard treatment guidelines (ADA & AACE Guidelines) followed in India, patients not responding to diet, exercise, monotherapy (Metformin), dual therapy (Sulfonylurea/ Biguanide), triple drug therapy can be recommended . 2. There is a sufficiently large population of patients not responding to first line and second line therapy, and hence requiring third line treatment 3. Further, the Subcommittee noted that as per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 4. However, this S.O. 822 does not mention the strengths of individual ingredients. Individual ingredients have their own maximum permissible dosage. Hence, strength of individual ingredients should be mentioned. Hence, the triple drug combination of FDC of "Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg" which is already approved by DCG(I) was found to be appropriate for patient compliance for this chronic disease. Hence, the Subcommittee is of the opinion that in the larger public interest, the FDC {Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg (SR)} need not be prohibited but needs to be Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target". Accordingly, apart from the already DCGI approved FDC of "Glibenclamide 5mg + Metformin 500mg + Pioglitazone 15 mg", the S.O. 822 may be amended as under; FDC of Glibenclamide + Metformin (SR) + Pioglitazone may be prohibited under Section 26A of the D&C act except for the following strength: Glibenclamide 5mg + Metformin 500mg (SR) + Pioglitazone 15mg Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target".

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 822(E)	Glibenclamide + Metformin (SR)+ Pioglitazone	Sun Pharma	Glibenclamide IP 5mg+Metformin HCL IP (SR) 500mg+Pioglitazone HCL IP eq. to Pioglitazone 15mg uncoated bilayered	The proposed FDC should not be used as first line of therapy for diabetes. The proposed FDC is indicated as third line treatment of type-II diabetes mellitus when diet, exercise and the single agents and second line therapy with two drugs do not result in adequate glycemic control.	i) Same as Annexure A ii) Not approved	The Subcommittee noted that S.O. 822 i.e. FDC of Glibenclamide + Metformin (SR) + Pioglitazone does not mention the strength of each ingredient. However, it mentions Metformin as Sustained Release (SR). The Subcommittee also noted that FDC of Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg film coated tablets is already approved by CDSCO on 23.02.2009 for the following indication: "As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control". Further, the Subcommittee observed that: 1. As per the standard treatment guidelines (ADA & AACE Guidelines) followed in India, patients not responding to diet, exercise, monotherapy (Metformin), dual therapy (Sulfonylurea/ Biguanide), triple drug therapy can be recommended . 2. There is a sufficiently large population of patients not responding to first line and second line therapy, and hence requiring third line treatment 3. Further, the Subcommittee noted that as per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 4. However, this S.O. 822 does not mention the strengths of individual ingredients. Individual ingredients have their own maximum permissible dosage. Hence, strength of individual ingredients should be mentioned. Hence, the triple drug combination of FDC of "Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg" which is already approved by DCG(I) was found to be appropriate for patient compliance for this chronic disease. Hence, the Subcommittee is of the opinion that in the larger public interest, the FDC {Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg (SR)} need not be prohibited but needs to be Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target". Accordingly, apart from the already DCGI approved FDC of "Glibenclamide 5mg + Metformin 500mg + Pioglitazone 15 mg", the S.O. 822 may be amended as under: FDC of Glibenclamide + Metformin (SR) + Pioglitazone may be prohibited under Section 26A of the D&C act except for the following strength: Glibenclamide 5mg + Metformin 500mg (SR) + Pioglitazone 15mg Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target".

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 822(E)	Glibenclamide + Metformin (SR)+ Pioglitazone	Windlas Biotech	Glibenclamide 5mg+ Metformin (SR) 500mg+ Pioglitazone 15mg tablet	Non insulin dependent diabetes mellitus patient poorly controlled with sulphonylurea or biguanide alone	i) Glucomust-PM tablet is used in the treatment of type-2 diabetes ii) Not submitted	The Subcommittee noted that S.O. 822 i.e. FDC of Glibenclamide + Metformin (SR) + Pioglitazone does not mention the strength of each ingredient. However, it mentions Metformin as Sustained Release (SR). The Subcommittee also noted that FDC of Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg film coated tablets is already approved by CDSCO on 23.02.2009 for the following indication: "As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control". Further, the Subcommittee observed that: 1. As per the standard treatment guidelines (ADA & AACE Guidelines) followed in India, patients not responding to diet, exercise, monotherapy (Metformin), dual therapy (Sulfonylurea/ Biguanide), triple drug therapy can be recommended . 2. There is a sufficiently large population of patients not responding to first line and second line therapy, and hence requiring third line treatment 3. Further, the Subcommittee noted that as per the Gazette notification no. 520 (E) dated 31.07.2013, safety concerns regarding Pioglitazone have been addressed and its suspension has been revoked with certain conditions. 4. However, this S.O. 822 does not mention the strengths of individual ingredients. Individual ingredients have their own maximum permissible dosage. Hence, strength of individual ingredients should be mentioned. Hence, the triple drug combination of FDC of "Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg" which is already approved by DCG(I) was found to be appropriate for patient compliance for this chronic disease. Hence, the Subcommittee is of the opinion that in the larger public interest, the FDC {Glibenclamide 5mg + Pioglitazone 15mg + Metformin 500mg (SR)} need not be prohibited but needs to be Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target". Accordingly, apart from the already DCGI approved FDC of "Glibenclamide 5mg + Metformin 500mg + Pioglitazone 15 mg", the S.O. 822 may be amended as under: FDC of Glibenclamide + Metformin (SR) + Pioglitazone may be prohibited under Section 26A of the D&C act except for the following strength: Glibenclamide 5mg + Metformin 500mg (SR) + Pioglitazone 15mg Regulated/ Restricted as under: "For treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target".
118	S.O. 822(E)	Glibenclamide + Metformin (SR)+ Pioglitazone	**In the larger public interest, the Subcommittee is of the opinion that S.O. 822 may be amended as under: FDC of "Glibenclamide + Metformin (SR) + Pioglitazone" needs to be restricted under Section 26A of the D&C act for the following strength: Glibenclamide 5mg + Metformin 500mg Sustained Release (SR) + Pioglitazone 15mg for "Treatment of type-2 diabetes mellitus (T2DM) when diet, exercise along with monotherapy and dual therapy does not achieve glycaemic target" as this FDC with the said strength is rational for the defined patient population. Further, the label and all the promotional literature including the package insert shall mention the precautions for individual drugs. Any other strength of FDC of Glibenclamide + Metformin (SR) + Pioglitazone is not recommended.**					

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 823(E)	Metformin (sustained release) 500mg + Pioglitazone 15 mg+ Glimepride 3mg	Mankind Pharma	Glimepiride IP 3mg+ Pioglitazone HCL IP eq. to Pioglitazone 15mg+ Metformin HCl IP 500mg (SR form) uncoated bilayered tablet	Glimestar PM 3 Tablet is used for Lower blood glucose in adults with type 2 diabetes mellitus, Type 2 diabetes mellitus	Glimestar-PM Tablets are indicated once daily, as an adjunct to diet and exercise, to lower blood glucose. It is indicated as second-line therapy when diet, exercise, and the single agents or dual therapy do not result in adequate glycemic control in patients with type-2 diabetes. ii.Not submitted	1. There are sufficient therapeutic options already available. 2. The FDC {Metformin (sustained release) 500mg + Pioglitazone 15 mg+ Glimepride 3mg} will result in Glimepiride dose of 12mg (exceeding the maximum permissible dose of 8mg per day) when Metformin dose of 2000mg is to be achieved with this FDC. Administration of the higher than the recommended maximum dose of Glimepiride may involve risk to human beings. 3. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 823(E)	Metformin (sustained release) 500mg + Pioglitazone 15 mg+ Glimepride 3mg	Cipla Ltd.	Glimepiride IP 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (ER) 500mg tablets	As 2nd line treatment of Type-2 Diabetes Mellitus when diet, exercise and the single agents and second line therapy with two drugs do not results in adequate glycemic control. It is not intended for use as first-line treatment.	i.Indication same as annexuer-A ii.Not submitted	1. There are sufficient therapeutic options already available. 2. The FDC {Metformin (sustained release) 500mg + Pioglitazone 15 mg+ Glimepride 3mg} will result in Glimepiride dose of 12mg (exceeding the maximum permissible dose of 8mg per day) when Metformin dose of 2000mg is to be achieved with this FDC. Administration of the higher than the recommended maximum dose of Glimepiride may involve risk to human beings. 3. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 823(E)	Metformin (sustained release) 500mg + Pioglitazone 15 mg+ Glimepride 3mg	Psychotropics India Ltd.	Glimepiride IP 3mg+ Pioglitazone HCl IP eq. to Pioglitazone 15mg+ Metformin Hcl IP (ER) 500mg tablets	Not submitted	Not submitted	1. There are sufficient therapeutic options already available. 2. The FDC {Metformin (sustained release) 500mg + Pioglitazone 15 mg+ Glimepride 3mg} will result in Glimepiride dose of 12mg (exceeding the maximum permissible dose of 8mg per day) when Metformin dose of 2000mg is to be achieved with this FDC. Administration of the higher than the recommended maximum dose of Glimepiride may involve risk to human beings. 3. Availability of multiple strengths can lead to medication error (prescribing, dispensing, administration) with risk of overdosing or under-dosing. There is no convincing scientific/ clinical evidence/ justification for the FDC.
119	S.O. 823(E)	Metformin (sustained release) 500mg + Pioglitazone 15 mg+ Glimepride 3mg	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and bearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 824(E)	Metformin (SR) 500mg+ Pioglitazone 5mg	-	-	-	-	1. There is no evidence for efficacy of 5mg Pioglitazone. 2. Pioglitazone 5mg strength is not approved by DCGI as a single ingredient for management of Type-2 diabetes as of now. 3. Hence, there is no therapeutic justification for this FDC. There is no convincing scientific/ clinical evidence/ justification for this FDC.
120	S.O. 824(E)	Metformin (SR) 500mg+ Pioglitazone 5mg	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 825(E)	Chloramphenicol +Beclomethasone +Clotrimazole +Lignocaine	FDC	Chloramphenicol IP 5%w/w+Beclomethasone Dipropionate IP 0.025%w/v+Clotrimazole IP 1%w/v+Lignocaine HCl IP 2%w/v ear drops	mixed bacterial and fungal infections in otitis externa	i.Indication same as Annexure-A ii. Marketed in Russia -candibiotic ear drops(Glenmark). Ukraine-candibiotic ear drops(Glenmark).	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Chloramphenicol), antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported do not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 825(E)	Chloramphenicol +Beclomethasone +Clotrimazole +Lignocaine	Elan Pharma	Chloramphenicol IP 5%w/v+Beclomethasone Dipropionate 0.025%w/v+Clomitrimazole IP 1%w/v+Lignocaine HCl IP 2%w/v ear drops	Otitis Externa	i.Indication same as Annexure-A. ii.Marketed as candibiotic ear drops(Glenmark). in United Kingdom, United States,Finald, France, Russia, UkarineChina, Maldives, Maritius, malaysia, Myanmar,Nepal, Vietnam, Botswana, Cambodia, Haiti, Dominica, Dominican Republic,Fiji, Ghana, Nigeria, Papua New Guinea, Rwanda, Samoa,Seychelles, South Africa, St.Lucia, Swaziland, Tanzania, bahrain, Zambia, Uzbekistan and Kazakhstan	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Chloramphenicol), antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 825(E)	Chloramphenicol +Beclomethasone +Cfotrimazole +Lignocaine	Akums Drugs	Chloramphenicol IP 5.0%w/v + Beclomethasone Propionate IP 0.025%w/v + Clotrimazole IP 1.0%w/v + Lignocaine HCl IP 2.0%w/v ear drops	treat patients suffering from fungal or bacterial infections of the middle or outer ear,known as otitis media and otitis externa respectively.	i.Indication same as Annexure-A ii.Not submitted.	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Chloramphenicol), antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 825(E)	Chloramphenicol +Beclomethasone +Clotrimazole +Lignocaine	Mankind Pharma	Chloramphenicol IP 5.0%w/v + Beclomethasone Propionate IP 0.025%w/v + Clotrimazole IP 1.0%w/v + Lignocaine HCl IP 2.0%w/v ear drops	Otitis Externa , Acute Otitis Media	i.Indication same as Annexure-A ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Chloramphenicol) , antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 825(E)	Chloramphenicol +Beclomethasone +Clotrimazole +Lignocaine	Roma Pharma	Chloramphenicol IP 5.0%w/v + Beclomethasone Propionate IP 0.025%w/v + Clotrimazole IP 1.0%w/v + Lignocaine HCl IP 2.0%w/v ear drops	To be used under the medical supervision.	i.Pacakge insert not submitted. ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Chloramphenicol) , antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 825(E)	Chloramphenicol +Beclomethasone +Clotrimazole +Lignocaine	Glenmark Pharmaceutical	Chloramphenicol IP 5% w/v+Beclomethasone Dipropionate IP 0.025%w/v +Clomitrimazole IP 1% w/v +Lidocaine BP 1.73%w/v Ear Drops	Not mentioned in Annexure A.	i.Not Submitted ii) Approved :Zambia, Malawi, Nepal, Myanmar, Cambodia, Maldives, Vietnam Kasakhstan ,Uzbekistan, Ukrain, Russia, Nigeria, Tanzania, Ghana, Mauritius Botswana, Cote D'Ivoire Dominican Republic ,Haiti. iii) Approved as IND : Zambia, Malawi Nepal, Myanmar, Cambodia, Maldives ,Vietnam, Kasakhstan, Uzbekistan, Ukrain, Russia, Nigeria Tanzania Ghana Mauritius Botswana Cote D'Ivoire Dominican Republic Haiti	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Chloramphenicol) , antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 825(E)	Chloramphenicol +Beclomethasone +Clotrimazole +Lignocaine	Sayora Pharma	Chloramphenicol IP 5%w/v+Beclomethasone dipropionate IP 0.025%w/v+ +Clomitrimazole IP 1%w/v+Lignocaine Hcl IP 2%w/v+Propylene glycol IP & Glycerine IP ear drops	Treatment of superficial bacterial and fungal infections of the external auditory canal and middle ear, caused by organisms susceptible to the action of Ofloxacin and Clotrimazole. By virtue of its three out of four active ingredients, the composition has antibacterial, antifungal and anti-inflammatory activity. Product is ideally suited to control bacterial and or fungal infection of ear.	i.Not Submitted ii) Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Chloramphenicol) , antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 825(E)	Chloramphenicol +Beclomethasone +Clotrimazole +Lignocaine	Pharmasynth Formulation	Chloramphenicol IP 5%w/v+Beclomethasone dipropionate IP 0.025%w/v+ +Clomitrimazole IP 1%w/v+Lignocaine Hcl IP 2%w/v+Propylene glycol IP & Glycerine IP ear drops	Treatment of otitis externa and acute otitis media with intact tympanic membrane.	i.indicated for the treatment and relief of inflammatory outer ear infections (otitis externa) and acute otitis media with intact tympanic membranes caused by bacteria and/or fungi. This product also relieves pain by functioning as a local anesthetic. For bacterial and fungal infections of the external ear. ii.Not available	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Chloramphenicol) , antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
121	S.O. 825(E)	Chloramphenicol +Beclomethasone +Clotrimazole +Lignocaine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	I) Indication as per package insert II) If marketing any where	
	S.O 826(E)	Chloramphenicol + Ofloxacin +Lignocaine + Glycerine and Propylene glycol	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining two antibacterials (Chloramphenicol & Ofloxacin) with a local anaesthetic (Lignocaine) in the FDC is liable to be misused and lead to emergence of resistance and adverse effects. 3. No study is found supporting the combined use of two antibacterials with a local anaesthetic. 4. There is no reasonable evidence of efficacy of Lignocaine in external ear canal (skin) in this FDC. There is no scientific/ clinical evidence/ justification for the FDC.
122	S.O 826(E)	Chloramphenicol + Ofloxacin +Lignocaine + Glycerine and Propylene glycol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O 827(E)	Chloramphennicol +Lignocaine +Betamethasone +Clotrimazole +Ofloxacin +Antipyrine	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining two antibacterials (Chloramphenicol & Ofloxacin) , antifungal (Clotrimazole) & steroid (Betamethasone) in the FDC is liable to be misused and lead to emergence of resistance and adverse effects. 3. No study is found supporting the combined use of anti-bacterials with an antifungal ingredient. 4. There is no reasonable evidence of efficacy of Lignocaine in external ear canal (skin) in this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
123	S.O 827(E)	Chloramphennicol +Lignocaine +Betamethasone +Clotrimazole +Ofloxacin +Antipyrine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 828(E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Ofloxacin) , antifungal (Clotrimazole), steroid (Betamethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & Clinical Trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
124	S.O. 828(E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 829(E)	Gentamicin Sulphate +Clotrimazole +Betamethasone +Lignocaine	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibiotic (Gentamicin Sulphate) , antifungal (Clotrimazole) and steroid (Betamethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. 5. Gentamicin is ototoxic and should not be used in tympanic membrane perforation. There is no sound scientific/ clinical evidence/ justification for the FDC.
125	S.O. 829(E)	Gentamicin Sulphate +Clotrimazole +Betamethasone +Lignocaine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 830(E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	Akums Drugs	Ofloxacin IP 0.3%w/v + Beclomethasone Dipropionate IP 0.025%w/v + Clotrimazole IP 1%w/v + Lignocaine HCl IP 2%w/v ear drops	Otitis Externa, Acute Otitis Media.	i.Not Mentioned ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibacterial (Ofloxacin) , antifungal (Clotrimazole) and steroid (Betamethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 830(E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	Coral Laboratories	Ofloxacin IP 0.3%w/v + Beclomethasone Dipropionate IP 0.025%w/v + Clotrimazole IP 1%w/v + Lignocaine HCl IP 2%w/v ear drops	Chronic Suppurative otitis media (CSOM), Acute otitis Media (AOM), Otalgia, Otitis Externa, Otorrhea.	i.Not Mentioned ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibacterial (Ofloxacin) , antifungal (Clotrimazole) and steroid (Betamethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 830(E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	Mankind Pharma	Ofloxacin IP 0.3%w/v + Beclomethasone Dipropionate IP 0.025%w/v + Clotrimazole IP 1%w/v + Lignocaine HCl IP 2%w/v ear drops	Otitis Externa, Acute Otitis Media.	i.Not Mentioned ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibacterial (Ofloxacin) , antifungal (Clotrimazole) and steroid (Betamethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and bearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 830(E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	Roma Pharma	Ofloxacin IP 0.3%w/v + Beclomethasone Dipropionate IP 0.025%w/v + Clotrimazole IP 1%w/v + Lignocaine HCl IP 2%w/v ear drops	As directed by physician	i.Not Mentioned ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibacterial (Ofloxacin) , antifungal (Clotrimazole) and steroid (Betamethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 830(E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	Sayora Pharma	Ofloxacin IP 0.3%w/v + Beclomethasone Dipropionate IP 0.025%w/v + Clotrimazole IP 1%w/v + Lignocaine HCl IP 2%w/v ear drops	Treatment of superficial bacterial and fungal infections of the external auditory canal and middle ear, caused by organisms susceptible to the action of Ofloxacin and Clotrimazole. By virtue of its three out of four active ingredients, the composition has antibacterial, antifungal and anti-inflammatory activity. Product is ideally suited to control bacterial and or fungal infection of ear.	i.Not Mentioned ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibacterial (Ofloxacin) , antifungal (Clotrimazole) and steroid (Betamethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 830(E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	Pharmasynth Formulation	Ofloxacin IP 0.3%w/v + Beclomethasone Dipropionate IP 0.025%w/v + Clotrimazole IP 1%w/v + Lignocaine HCl IP 2%w/v ear drops	Treatment of otitis externa and acute otitis media with intact tympanic membrane.	i.Not Mentioned ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibacterial (Ofloxacin) , antifungal (Clotrimazole) and steroid (Betamethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 830(E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	Skan Research	Ofloxacin IP 0.3%w/v + Beclomethasone Dipropionate IP 0.025%w/v + Clotrimazole IP 1%w/v + Lignocaine HCl IP 2%w/v ear drops	The treatment of superficial bacterial and fungal infections of the external auditory canal and middle ear caused by organisms susceptible to the action of Ofloxacin and Clotrimazole	i.Indication same as annexure-A. ii.Not submitted.	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibacterial (Ofloxacin) , antifungal (Clotrimazole) and steroid (Betamethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
126	S.O. 830 (E)	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 831(E)	Beclomethasone +Clotrimazole +Chloramphenicol +Gentamycin +Lignocaine	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining two antibiotics (Gentamicin Sulphate, Chloramphenicol) , antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & clinical trials reported did not justify this FDC. 5. Gentamicin is ototoxic and should not be used in tympanic membrane perforation. There is no sound scientific/ clinical evidence/ justification for the FDC.
127	S.O. 831(E)	Beclomethasone +Clotrimazole +Chloramphenicol +Gentamycin +Lignocaine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 832(E)	Flunarizine + Paracetamol+ Domperidone	Akums Drugs	Flunarizine dihydrochloride IP eq. To Flunarizine 5mg + Paracetamole IP 500mg+ Domperidone Maleate IP eq. To Domperidone 10mg film coated tablet	Used in prophylaxis of migraine. During hearing, the appellant informed that they wish to change the idictaions to "For acute attack of migraine".	i)The package insert is of other combinations ii) Not submitted	1. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment. 2. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 832(E)	Flunarizine + Paracetamole+ Domperidone	Mankind Pharma	Flunarizine Dihydrochloride BP eq. to Flunarizine 5mg+ Domperidone IP 10mg+ Paracetmol IP 325mg uncoated tablet	Used for symptomatic management of acute attack of migraine	i) Same ii) Not approved	1. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment. 2. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 832(E)	Flunarizine + Paracetamole+ Domperidone	Windlas Biotech	Flunarizine Dihydrochloride BP eq. to Flunarizine 5mg+ Domperidone IP 10mg+ Paracetmol IP 325mg uncoated tablet	Anti-Migraine	i) same ii) Not mentioned	1. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment. 2. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 832(E)	Flunarizine + Paracetamole+ Domperidone	Tidal Laboratories	Flunarizine Dihydrochloride BP eq. to Flunarizine 5mg+ Domperidone IP 10mg+ Paracetmol IP 500mg uncoated tablet	Acute Migraine	i)same ii) Not approved	1. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment. 2. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O. 832(E)	Flunarizine + Paracetamole+ Domperidone	Horizon Bioceuticals	Flunarizine Dihydrochloride BP eq. to Flunarizine 5mg+ Paracetamole IP 325mg+ Domperidone IP 10mg uncoated tablet	Treatment of acute migraine attack.	i)same ii) Not submitted	1. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment. 2. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 832(E)	Flunarizine + Paracetamole+ Domperidone	Meridian Medicare	Flunarizine Dihydrochloride BP eq. to Flunarizine 5mg+ Paracetamole IP 325mg+ Domperidone IP 10mg tablet	Not specified	i) Not submitted ii) Not submitted	1. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment. 2. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
128	S.O. 832(E)	Flunarizine + Paracetamole+ Domperidone	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 833(E)	Rabeprazole + Zinc carnosine	-	-	-	-	1. Zinc carnosine, with unsubstantiated claims for use in Gastritis, Dyspepsia and Gastric ulcers, is inappropriate. Use of zinc in peptic ulcer disease is not based on evidence. 2. No published literature supporting the FDC. 3. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
129	S.O. 833(E)	Rabeprazole + Zinc carnosine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 834(E)	Magaldrate + Famotidine + Simethicone	-	-	-	-	1. No evidence of efficacy exists supporting the use of triple drug combination. 2. Antacids like magaldrate are known to reduce bioavailability for famotidine. 3. Simethicone an anti-foaming ingredient is used to reduce bloating sensation due to excessive gas production. Peptic ulcer is not associated with excessive gas formation. 4. There is mismatch in the dosing schedule of the different ingredients {famotidine once a day, simethicone four times a day and magaldrate as and when needed (SOS)}. 5. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
130	S.O. 834(E)	Magaldrate + Famotidine + Simethicone	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 835(E)	Cyproheptadine + Thiamine	-	-	-	-	1. Cyproheptadine is used as an appetite stimulant and Thiamine is a vitamin. There is no clinical justification of combining the two drugs. 2. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
131	S.O. 835(E)	Cyproheptadine + Thiamine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	I. Indication as per package insert II. If marketing anywhere	
	S.O. 836(E)	Magaldrate + Ranitidine + Pancreatin + Domperidone	-	-	-	-	1. The individual ingredients have specific uses but their combination in this FDC does not have any valid indication. 2. Antacids like magaldrate are known to reduce bioavailability for ranitidine. 3. There is mismatch in the dosing schedule of the different ingredients (ranitidine twice a day, pancreatin along with principal meals and magaldrate as and when needed (SOS)). 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
132	S.O. 836(E)	Magaldrate + Ranitidine + Pancreatin + Domperidone	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 837(E)	Ranitidine + Magaldrate + Simethicone	-	-	-	-	1. No evidence of efficacy exists supporting the use of triple drug combination. 2. Antacids like magaldrate are known to reduce bioavailability for ranitidine. 3. Simethicone an anti-foaming ingredient is used to reduce bloating sensation due to excessive gas production. Peptic ulcer is not associated with excessive gas formation. 4. There is mismatch in the dosing schedule of the different ingredients {ranitidine once a day, simethicone four times a day and magaldrate as and when needed (SOS).}. 5. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
133	S.O. 837(E)	Ranitidine + Magaldrate + Simethicone	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 838(E)	Magaldrate + papain+ Fungal diastase + Simethicone	Skan Research	Magaldrate 400mg+ Papain 60mg+ Alpha Amylase (1:2000) 20mg+ Simehticone 25mg film coated tablet	• Used as an adjunct to other drugs for the relief of peptic ulcer pain and to promote the healing of peptic ulcers. • Antacids also are used for the relief of esophageal reflux, acid indigestion, heart burn, dyspepsia and sour stomachfor the prevention of stress ulceration and GI bleeding to reduce the risk associated with gastric aspiration and for the management of hyperphosphatemia. • Flatulence, • Functional gastric bloating, • Post operative gas pain	i) VEPZYME Tablet is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms: • Digestion • Painful pressure • Herpes zoster • Hiccoughs • Sore throat and throat swelling • Hiccups • Swelling in the abdomen • Starch degrading enzyme • VEPZYME Tablet may also be used for purposes not listed here. ii) Not submitted	1. All the conditions listed as indications do not co-exist and patient will be exposed to unwanted drugs. For example Papain and alpha amylase are digestive enzymes. Simethicone an anti-foaming ingredient is used to reduce bloating sensation due to excessive gas production. 2. No published literature supporting the mechanism of action or efficacy for the combination is available. 3. Use of Magaldrate is not justified in prevention of stress ulceration and GI bleeding. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
134	S.O. 838(E)	Magaldrate + papain+ Fungal diastase + Simethicone	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 839(E)	Rabeprazole + zinc + Domperidone	-	-	-	-	1. No published literature supporting the FDC. 2. Use of zinc in peptic ulcer disease is not based on evidence. 3. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
135	S.O. 839(E)	Rabeprazole + zinc + Domperidone	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 840(E)	Famotidine + Oxytacaine + Magaldrate	-	-	-	-	1. No evidence of efficacy exists supporting the use of triple drug combination. 2. Antacids like magaldrate are known to reduce bioavailability for famotidine. 3. Combining a drug like oxytacaine which is used for symptomatic relief of GERD with an antiulcer agent like famotidine (that requires more prolong therapy) is inappropriate. 4. There is mismatch in the dosing schedule of the different ingredients {(famotidine once a day, oxytacaine four times a day and magaldrate as and when needed (SOS)}. 5. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
136	S.O. 840(E)	Famotidine + Oxytacaine + Magaldrate	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 841(E)	Ranitidine+ Domperidone+ Semithicone	Horizon Bioceuticals	Ranitidine HCl IP eq. to Ranitidine 150mg+ Domperidone IP 10mg+ Simethicone (Activated) IP 20mg film coated tabelt	heartburn, nausea	i) same as Annexure A ii) Not submitted	1. All the conditions listed as indications do not co-exist and patient will be exposed to unwanted drugs. Simethicone an anti-foaming ingredient is used to reduce bloating sensation due to excessive gas production which may not be associated with acidity and heart burn. 2. Each of the conditions listed is to be treated specifically by a single individual agent. 3. No published literature supporting the mechanism of action or efficacy for the combination is available. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
137	S.O. 841(E)	Ranitidine+ Domperidone+ Semithicone	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 842(E)	AlginicAcid+ Sodium Bicarbonate+ Dried Aluminium Hydroxide+ Magnesium Hydroxide	-	-	-	-	This FDC was earlier discussed by previous Committee on 05.09.2014 "The committee opined that internationally there is no authentic reference for inclusion of sodium bicarbonate in a combined antacid formulation. Sodium bicarbonate is a systemic alkalinizer and not a locally acting antacid. There is risk of systemic adverse effects on chronic use of such products. Hence the committee did not recommend such FDC". The Subcommittee concurred with the above and notes that: 1. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
138	S.O. 842(E)	AlginicAcid+ Sodium Bicarbonate+ Dried Aluminium Hydroxide+ Magnesium Hydroxide	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 843(E)	Clidinium + Paracetamol + Dicyclomine + Activated Dimethicone	Lark Laboratories	Clidinium + Paracetamol + Dicyclomine + Activated Dimethicone	Gastro-Intestinal spasm and flatulence.	i) Not submitted ii) Not submitted	1. Each ingredient has different therapeutic use and FDC will lead to misuse and unnecessary exposure to multiple drugs and their side effects. 2. Paracetamol is not indicated for spasms of GI origin and flatulence. There is no sound scientific/ clinical evidence/ justification for the FDC.
139	S.O. 843(E)	Clidinium + Paracetamol + Dicyclomine + Activated Dimethicone	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 844(E)	Furazolidone + Metronidazole + Loperamide	-	-	-	-	1. Loperamide, the antimotility drug will cause toxic megacolon in infective diarrhoea. 2. Loperamide is contra-indicated in infective diarrhea and in patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella, and Campylobacter as it reduces the clearance of pathogens. Hence there is no rationale for combining with antibacterials in an FDC. 3. In bacterial diarrhoea only anti-bacterial drug is effective and antiamoebic drug is useless and vice versa. But amoebiasis and bacterial diarrhoea rarely coexist. Hence there is unnecessary exposure to the one or other ingredient resulting in increased chances of ADRs. 4. Use of antimotility and anti infective agent in a FDC cannot be justified because the former is made for symptomatic relief and is given as and when needed (SOS) while the latter treating an infection that requires repeated dosing (furazolidine is to be given four times a day) for few days. 5. Furazolidone is not a drug of choice for infective diarrhoea and better alternatives are available. Its use is associated with side effects. 6. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
140	S.O. 844(E)	Furazolidone + Metronidazole + Loperamide	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 845(E)	Rabeprazole + Diclofenac + Paracetamol	-	-	-	-	1. Pharmacokinetically inappropriate as each ingredient has different dosing schedule/dosing requirement (diclofenac 2-3 times a day, paracetamol 3-4 times a day and rabeprazole once a day). 2. Rabeprazole cannot prevent intestinal injury caused by Diclofenac. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
141	S.O. 845(E)	Rabeprazole + Diclofenac + Paracetamol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 846(E)	Ranitidine + Magaldrate	-	-	-	-	1. Antacids like magaldrate are known to reduce bioavailability for ranitidine. 2. There is mismatch in the dosing schedule of the different ingredients {ranitidine once a day and magaldrate as and when needed (SOS)}. There is no convincing scientific/ clinical evidence/ justification for the FDC.
142	S.O. 846(E)	Ranitidine + Magaldrate	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 847(E)	Norfloxacin+ Metronidazole + Zinc Acetate	-	-	-	-	1. Both the ingredients have different therapeutic indications. Diarrhoea of mixed infection (bacterial and parasitic) is uncommon. 2. Use of this FDC in diarrhoea will result in overuse of drugs and will result in resistance and increase in ADRs. 3. Pharmacokinetic mismatch: Metronidazole is given three times a day whereas Norfloxacin is given twice a day. 4. There is no medical condition which requires a co-administration of Norfloxacin and Zinc acetate. The latter has no role in the treatment of Gastrointestinal infections. 5. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
143	S.O. 847(E)	Norfloxacin+ Metronidazole + Zinc Acetate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 848(E)	Zinc Carnosine+ Oxetacaine	-	-	-	-	1. No identifiable indication for this FDC. 2. Combining a drugs like oxetacaine which is used for symptomatic relief of GERD with Zinc carnosine with unsubstatiated claims for use in Gastritis, Dyspepsia and Gastric ulcers is inappropriate. 3. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
144	S.O. 848(E)	Zinc Carnosine+ Oxetacaine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 849(E)	Oxetacaine + Magaldrate + Famotidine	-	-	-	-	1. No evidence of efficacy exists supporting the use of triple drug combination. 2. Antacids like magaldrate are known to reduce bioavailability for famotidine. 3. Combining a drug like oxetacaine which is used for symptomatic relief of GERD with an antiulcer agent like famotidine (that requires more prolong therapy) is inappropriate. 4. There is mismatch in the dosing schedule of the different ingredients (famotidine once a day, oxytacaine four times a day and magaldrate SOS). 5. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
145	S.O. 849(E)	Oxetacaine + Magaldrate + Famotidine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 850(E)	Pantoprazole (as Enteric Coated Tablet)+ Zinc Carnosine (as Film Coated Tablets)	Comed Chemicals Ltd.	Pantoperazole 40mg + Zinc carnosine 75mg tablet	Gastritis, Epigastritis pain, Co-prescription with Antihypertensive, Anti diabetic, Antibiotics and NSAIDs	i) Same as Annexure A ii) Not submitted	1. No published literature supporting the FDC. 2. Use of Zinc carnosine with unsubstatiated claims in Gastritis, Dyspepsia and Gastric ulcers is inappropriate. Use of zinc in peptic ulcer disease is not based on evidence. 3. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
146	S.O. 850(E)	Pantoprazole (as Enteric Coated Tablet)+ Zinc Carnosine (as Film Coated Tablets)	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package Insert ii. If marketing anywhere	
	S.O. 851(E)	Zinc Carnosine+ Magnesium Hydroxide + Dried Aluminium Hydroxide + Simethicone	-	-	-	-	1. Pharmacodynamically inappropriate: Magnesium hydroxide and Dried aluminium Hydroxide are used in the treatment of dyspepsia and gastritis. Simethicone is anti-flatulent while use of zinc in peptic ulcer disease is not based on evidence. 2. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
147	S.O. 851(E)	Zinc Carnosine+ Magnesium Hydroxide + Dried Aluminium Hydroxide + Simethicone	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

ME.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 852(E)	Zinc Carnosine+ Sucralfate	-	-	-	-	1. Use of Zinc carnosine with unsubstatiated claims in Gastritis, Dyspepsia and Gastric ulcers is inappropriate. Use of zinc in peptic ulcer disease is not based on evidence. 2. Though sucralfate is used for peptic ulcer diseases, combining it with Zinc Carnosine in the FDC is inappropriate. 3. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
148	S.O. 852(E)	Zinc Carnosine+ Sucralfate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

ME.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 853(E)	Mebeverine Hydrochloride & Inner HPMC capsule (Streptococcus Faecalis +Clostridium butyricum +Bacillus mesentricus+Lactic Acid Bacillus)	-	-	-	-	The indications for Mebeverine (which is an anti spasmodic agent) and other ingredients of the FDC are different. There is no rationale of combining Mebeverine with other ingredients. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
149	S.O. 853(E)	**Mebeverine Hydrochloride & Inner HPMC capsule (Streptococcus Faecalis +Clostridium butyricum +Bacillus mesentricus+Lactic Acid Bacillus)**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

314

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 854(E)	Clindamycin + Clotrimazole + Lactic Acid Bacillus	Akums Drugs	Clindamycin Phosphate BP 100mg+Clotrimazole Phosphate IP 200mg+Lactic Acid Bacillus 1.5 billion spores soft gelatin capsules	Used for the treatment of Trichomoniasis, Candida vulvitis, mycoses, Vaginal Candidiasis, Bacterial Vaginitis, Mixed Vaginal Infections and non specific vaginitis.	i. Indication Same as Annexure-A ii. Not approved	1. The FDC likely to increase the anti-microbial resistance. 2. As per the National & International Standard Treatment guidelines for the management of genital tract infection, the anti-microbial combination recommended for the vaginal discharge are Tinidazole + Clindamycin + Fluconazole. 3. This combination is not as per standard treatment guidlines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 854(E)	Clindamycin + Clotrimazole + Lactic Acid Bacillus	Elnova Pharma	Clindamycin Phosphate IP eq. to Clindamyin 100mg+Clotrimazole Phosphate IP 200mg+Lactic Acid Bacillus 1.5 billion spores soft gelatin capsules	Not mentioned	i. Indication Same as Annexure-A ii. Not approved	1. The FDC likely to increase the anti-microbial resistance. 2. The National & International Standard Treatment guidelines for the management of genital tract infection, the anti-microbial combination recommended for the vaginal discharge are Tinidazole + Clindamycin + Fluconazole. There is no sound scientific/ clinical evidence/ justification for the FDC.
150	S.O. 854(E)	Clindamycin + Clotrimazole + Lactic Acid Bacillus	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

me

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 855(E)	Sildenafil citrate IP eq. to Sildenafil + Estradiol Valerate USP	Akums Drugs	Sildenafil citrate IP eq. to Sildenafil 25 mg Estradiol Valerate USP 1 mg	Treatment of infertility as assisted reproductive treatment for women.	i. Indication Same as Annexure-A ii. Not approved	1. Sildenafil has potential for cardiac risk in patients with pre-existing cardiovascular disease. 2. No clinical studies are found supporting this combination. The appellant presented literature on rationale for using Sildenafil and Estrogen for infertility treatment in women. However, they did not provide sufficient evidence for benefit of this FDC in comparison to Sildenafil/ Estradiol alone. 3. This combination is not as per standard tretment guidlines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 855(E)	Sildenafil citrate IP eq. to Sildenafil +Estradiol Valerate USP	TTK	Sildenafil citrate IP eq. to Sildenafil 25 mg Estradiol Valerate USP 2 mg	Infertility treatment in women	Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Indicated for treatment for endometrial thinning thereby enhancing receptivity in ovulation induction cycle, multiple failed cycles of ART, IUI, IVF and ICSI cycles and elderly infertile patients. ii.Not submitted	1. Sildenafil has potential for cardiac risk in patients with pre-existing cardiovascular disease. 2. No clinical studies are found supporting this combination. The appellant presented literature on rationale for using Sildenafil and Estrogen for infertility treatment in women. However, they did not provide sufficient evidence for benefit of this FDC in comparison to Sildenafil/ Estradiol alone. 3. This combination is not as per standard therapeutic guidlines. There is no sound scientific/ clinical evidence/ justification for the FDC.
151	**S.O. 855(E)**	**Sildenafil citrate IP eq. to Sildenafil +Estradiol Valerate USP**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 856(E)	Clomifene Citrate +Ubidecarenone +Zinc +Folic Acid +Methylcobalamin +Pyridoxine +Lycopene +Selenium+ LevocarnitineTartra te+ L-Arginine	Wanbury	Clomifene Citrate IP 25 mg Ingredient(For Tablet B) Quantity Ubidecarenine USP 60 mg Zinc Sulphate Monohydrate IP 66 mg Folic Acid IP 5 mg Methylcobalamin USP 1500 mcg Pyridoxine Hydrochloride IP 1.5 mg Lycopene USP 4 mg Selenium (As Sodium Selenite Pentahydrate BP) 200 mcg Levocarnitine Tartarate 50 mg L-Arginine IP 20 mg	Indicated for treatment of male infertility with testosterone deficiency.	i. Indication Same as Annexure-A ii. Not approved	1. No published literature supporting the combination of clomifene with multivitamins and antioxidants for treatment of male infertility. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 856(E)	Clomifene Citrate +Ubidecarenone +Zinc +Folic Acid +Methylcobalamin +Pyridoxine +Lycopene +Selenium+ LevocarnitineTartrate+ L-Arginine	Creative Healthcare	Each kit contains: A)Clomifene Citrate IP 25 mg B) Ubidecarenine USP 60 mg Zinc Sulphate Monohydrate IP 66 mg Folic Acid IP 5 mg Methylcobalamin USP 1500 mcg Pyridoxine Hydrochloride IP 1.5 mg Lycopene USP 4 mg Selenium (As Sodium Selenite Pentahydrate BP) 200 mcg Levocarnitine Tartarate 50 mg L-Arginine IP 20 mg	Used for the treatment of ovulatory dysfunction in women desiring pregnancy, Infertility in men.	i. Not submitted ii. As per firm, this FDc is marketed in India.	1. No published literature supporting the combination of clomifene with multivitamins and antioxidants for treatment of male infertility. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
152	S.O. 856(E)	Clomifene Citrate +Ubidecarenone +Zinc +Folic Acid +Methylcobalamin +Pyridoxine +Lycopene +Selenium+ LevocarnitineTartrate+ L-Arginine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 857(E)	Thyroxine + Pyridoxine + Folic Acid	-	-	-	-	1. Thyroxine has narrow therapeutic index. 2. Hence, as per guidelines, it cannot be combined in an FDC. 3. There is no rationale for this FDC and this combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
153	S.O. 857(E)	Thyroxine + Pyridoxine + Folic Acid	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 858(E)	Gentamycin+ Dexamethasone+ Chloramphenicol+ Tobramycin+ Ofloxacin	-	-	-	-	1. There is no rationale of having four antimicrobials (Gentamicin, Chloramphenicol, Tobramycin, Ofloxacin) in an FDC. 2. Having two antimicrobials from the same group (Gentamicin and Tobramicin) is not rational and may have risks. 3. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
154	S.O. 858(E)	Gentamycin+ Dexamethasone+ Chloramphenicol+ Tobramycin+ Ofloxacin	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 859(E)	Dextromethorphan+ Levocetirizine+ Phenylephrine+ Zinc	Akums Drugs	Dextromethorphan HCl IP 10mg+ Levocetirizine HCl IP 2.5mg+ Phenylephrine HCl IP 5mg+ Zinc Gluconate USP eq. To Elemental Zinc 7.5mg per 5ml syrup	Indicated of cough associated with nasal congestion as in respiratory tract infection/allergies	i) Indication same as Annexure-A ii) Not Approved	1. Pharmacokinetically incompatible FDC: Levocetirizine is given once a day whereas Dextromethorphan and Phenylephrine are given three-four times a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. Dextromethorphan and Levocetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
155	S.O. 859(E)	Dextromethorphan+ Levocetirizine+ Phenylephrine+ Zinc	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 860(E)	Nimesulide+ Loratadine+ Phenylephrine+ Ambroxol	Akums Drugs	Nimesulide BP 100mg+ Loratadine USP 2.5mg+ Phenylephrine HCl IP 10mg+ Ambroxol HCl IP 15mg film coated tablet	This product has formulated for proposed combination is indicated for cold and flu relief	i)Indication same as Annexure-A ii) Not Submitted	The Subcommittee noted that FDC of Nimesulide+ Levocetirizine was deliberated by SEC (Pulmonary) in its meeting held on 24.09.2014: "The SEC committee examined and opined that the FDC is not rational as Levocetirizine is anti-histaminic whereas Nimesulide is an antipyretic-analgesic and the combination is likely to be misused/overused in situations where single drug is required. Further this FDC is not approved anywhere in the world. Hence the SEC committee did not recommend for its continued marketing in the country." The DTAB Subcommittee concured with the opinion of SEC and opined that the same applies to Loratadine. It further noted that: 1. FDC is pharmacokinetically incompatible as dosing interval of Loratadine is once a day, that of Nimesulide and Ambroxol is two times and three times a day respectively. 2. Nimesulide use in the E.U. is limited to ≤15 days due to the risk of hepatotoxicity. 3. There is no definitive evidence of Ambroxol in common cold (it is not recommended in guidelines). 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 5. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 860(E)	Nimesulide+ Loratadine+ Phenylephrine+ Ambroxol	Windlas Biotech	Nimesulide 100mg+ Loratadine 5mg+ Phenylephrine HCl 20mg+ Ambroxol HCl 30mg tablets	for relief of irritating and troublesome cough fever and headache	i) Indication same as Annexure-A ii) Not submitted	The Subcommittee noted that FDC of Nimesulide+ Levocetirizine was deliberated by SEC (Pulmonary) in its meeting held on 24.09.2014: "The SEC committee examined and opined that the FDC is not rational as Levocetirizine is anti-histaminic whereas Nimesulide is an antipyretic-analgesic and the combination is likely to be misused/overused in situations where single drug is required. Further this FDC is not approved anywhere in the world. Hence the SEC committee did not recommend for its continued marketing in the country." The DTAB Subcommittee concured with the opinion of SEC and opined that the same applies to Loratadine. It further noted that: 1. FDC is pharmacokinetically incompatible as dosing interval of Loratadine is once a day, that of Nimesulide and Ambroxol is two times and three times a day respectively. 2. Nimesulide use in the E.U. is limited to ≤15 days due to the risk of hepatotoxicity. 3. There is no definitive evidence of Ambroxol in common cold (it is not recommended in guidelines). 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 5. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
156	S.O. 860(E)	Nimesulide+ Loratadine+ Phenylephrine+ Ambroxol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 861(E)	Bromhexine+ Phenylephrine+ Chlorpheniramine Maleate	Akums Drugs	Bromhexine HCl IP 16mg/4mg+ Phenylephrine HCl IP 5mg/5mg+ Chlorpheniramine Maleate IP 4mg/2mg film coated tablet	Cough and cold with mild respiratory congestion. (Indications as informed during presentation)	i) Indication same as Annexure-A ii) Not submitted	1. Pharmacodynamically antagonistic as Bromhexine is a mucolytic agent and liquifies the mucus whereas Chlorpheniramine maleate is a cough suppressant so expulsion of mucus secretion would be hampered. 2. There is no definitive evidence of Bromhexine in common cold (It is not recommended in guidelines). 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 861(E)	Bromhexine+ Phenylephrine+ Chlorpheniramine Maleate	Tidal Laboratories	Bromhexine HCl IP 4mg+ Phenylephrine HCL IP 12.5mg+ Chlorpheniramine Maleate IP 2mg uncoated dispersible tablet	Cough and cold with mild respiratory congestion.	i) Indication same as Annexure-A ii) Not submitted	1. Pharmacodynamically antagonistic as Bromhexine is a mucolytic agent and liquifies the mucus whereas Chlorpheniramine maleate is a cough suppressant so expulsion of mucus secretion would be hampered. 2. There is no definitive evidence of Bromhexine in common cold (It is not recommended in guidelines). 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 861(E)	Bromhexine+ Phenylephrine+ Chlorpheniramine Maleate	Merck Ltd.	Bromhexine HCl IP 4mg+ Phenylephrine HCL IP 5mg+ Chlorpheniramine Maleate IP 2mg uncoated dispersible tablet	Symptomatic treatment of productive cough associated with nasal congestion in cold and URTI.	i) Not submitted ii) Not submitted	1. Pharmacodynamically antagonistic as Bromhexine is a mucolytic agent and liquifies the mucus whereas Chlorpheniramine maleate is a cough suppressant so expulsion of mucus secretion would be hampered. 2. There is no definitive evidence of Bromhexine in common cold (It is not recommended in guidelines). 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
157	S.O. 861(E)	**Bromhexine+ Phenylephrine+ Chlorpheniramine Maleate**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 862(E)	Dextromethorphan+ Bromhexine+ Guaiphenesin	Akums Drugs	Dextromethorphan HBr IP 10mg+ bromhexine HBr IP 2mg+ Guaiphenesin IP 100mg soft gelatin capsule	Secretolytic therapy in acute and chronic bronchopulmonary disease associated with abnormal mucus secretion and impaired mucus secretion and impaired mucus transport. Reduces the viscosity of uninfected bronchial secretions in bronchial asthma, chronic bronchitis, cystic fibrosis and pulmonary emphysema. Temporary relieves cough due to minor throat and bronchial irritation as many occur with the common cold or inhaled irritants.	i) Indication same as Annexure-A ii) Not submitted	1.Pharmacodynamically inappropriate: Bromhexine and Guaiphenesin are Mucolytic/ Expectorant whereas Dextromethorphan inhibits the cough reflex, which hampers expulsion of secretions. Therefore, Mucolytic and expectorant should not be combined with cough suppressant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. Patient population is not well defined. 4. There is no definitive evidence of Bromhexine in common cold. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 862(E)	Dextromethorphan+ Bromhexine+ Guaiphenesin	Elnova Pharma	Dextromethorphan HCl IP 10mg+ Bromhexine HCl IP 2mg+ Guaiphenesin IP 100mg soft gelatin capsules	Not mentioned	i) In the package insert mentioned that relieving symptoms of sinus congstion, runny nose, sneezing, cough and throat and airway irritaion due to colds, upper respitratory infections and allergies. Further stated that it is an antihistamine, decongestant, cough suppressant and expoectorant combination. ii) Sri lanka, Bhutan, Nepal, Cambodia, Ghana, Nigeria, Uganda and all Asian countries	1.Pharmacodynamically inappropriate: Bromhexine and Guaiphenesin are Mucolytic/ Expectorant whereas Dextromethorphan inhibits the cough reflex, which hampers expulsion of secretions. Therefore, Mucolytic and expectorant should not be combined with cough suppressant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no definitive evidence of Bromhexine in common cold. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
158	S.O. 862(E)	Dextromethorphan+ Bromhexine+ Guaiphenesin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 863(E)	Paracetamol+ Loratadine+ Phenylephrine+ Dextromethorphan+ Caffeine	Akums Drugs	Paracetmol IP 325mg+ Phenylephrine HCl 10mg+ Loratidine 3.3mg+ Dextromethorphan 10mg+ Caffeine 30mg uncoated tablets	It is used for treatment when change of season incidence of common cold increase in children	i) Indication mentioned in package insert do not match as Annexure A. In package insert additional indication of Allergic rhinitis, Urticaria, fever, Headache, Bodyache and Headache associated with sinusitis are mentioned. ii) Not Approved	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Pharmacokinetic incompatibility as dosing schedule of loratadine is once a day whereas that of other ingredients is three/four times a day. 3. Dextromethorphan and Loratidine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 4. Patient population not well defined. 5. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
159	S.O. 863(E)	**Paracetamol+ Loratadine+ Phenylephrine+ Dextromethorphan+ Caffeine**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 864(E)	Nimesulide+ Phenylephrine+ Ceffeine+ Levocetirizine	Akums Drugs	Nimesulide 100mg+ Phenylephrine HCl IP 10mg+ Caffeine (Anhydrous) IP 30mg+ Levocetirizine Dihydrous IP 5mg uncoated tablet	Nasal congestion, common cold, rhinorrhoea, fever with common cold, allergic cough.	i) Indication mentioned in package insert do not match as above. Ii) Not Available	The Subcommittee noted that FDC of Nimesulide+ Levocetirizine was deliberated by SEC (Pulmonary) in its meeting held on 24.09.2014: "The SEC committee examined and opined that the FDC is not rational as Levocetirizine is anti-histaminic whereas Nimesulide is an antipyretic- analgesic and the combination is likely to be misused/overused in situations where single drug is required. Further this FDC is not approved anywhere in the world. Hence the SEC committee did not recommend for its continued marketing in the country." The DTAB Subcommittee concured with the opinion of SEC and further noted that: 1. Nimesulide use in the E.U. is limited to ≤15 days due to the risk of hepatotoxicity. 2. There is pharmacokinetic incompatibility (Levocetirizine is once a day, Nimesulide is twice a day & Phenylephrine is 3-4 times a day) 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
160	S.O. 864(E)	Nimesulide+ Phenylephrine+ Ceffeine+ Levocetirizine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 865(E)	Azithromycin+ Acebrophyline	Akums Drugs	Each Film coated Tablet Contains Azithromycin IP as dihydrate Eq. to Anhydrous Azithromycin 250/500mg Acebrophylline 100mg/100mg	Combination is indicated for the treatment of patients with mild to moderate respiratory tract infection associated with excessive mucous secretion.	i. Same as Annexure A. ii. NA	1. Pharmacodynamically inappropriate FDC: There is no justification in combining mucolytic ingredient (Acebrophyline) with an antibiotic (Azithromycin), as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient. 2. Acebrophylline being a mucolytic and bronchodilator agent, has no added advantage in the anti-microbial activity. 3. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. 4. There is pharmacokinetic incompatibility as dosing schedule of Azithromycin is once a day and that of Acebrophylline is twice a day. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
161	S.O. 865(E)	Azithromycin+ Acebrophylline	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 866(E)	Diphenhydramine+ Terpine+ Ammonium Chloride+ Sodium Chloride+ Menthol	Biogenetic Drugs	Diphenhydramine HCl IP 12.5mg+ Terpine HCL IP 7.5mg+ Ammonium Chloride IP 125mg+ Sodium Citrate IP 55mg per 5ml syrup+ Menthol	Broad spectrum antibiotic	i) Pacakge insert has not submitted. ii) Not submitted	For the indication mentioned by the appellant i.e. Broad spectrum antibiotic, this FDC is irrelevant, irrational and hence not recommended. The Subcommittee further noted that: 1. The FDC per se is pharmacodynamically antagonistic and hence inappropriate. (Ammonium chloride and Sodium citrate are expectorants whereas Diphenhydramine is cough suppressant and soo expulsion of secretions would be hampered.) 2. Terpine has been discontinued since 1990's due to lack of efficacy data. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 866(E)	Diphenhydramine+ Terpine+ Ammonium Chloride+ Sodium Chloride+ Menthol	Smilax Healthcare	Diphenhydramine HCl IP 12.5mg+ Terpine Hydrate USP 7.5mg+ Ammonium Chloride IP 125mg+ Sodium Chloride IP 55mg+ Menthol IP 1.5mg per 5ml syrup	Broad spectrum antibiotic	i) Package insert not submitted. ii) Not submitted	For the indication mentioned by the appellant i.e. Broad spectrum antibiotic, this FDC is irrelevant, irrational and hence not recommended. The Subcommittee further noted that: 1. The FDC per se is pharmacodynamically antagonistic and hence inappropriate. (Ammonium chloride and Sodium citrate are expectorants whereas Diphenhydramine is cough suppressant and soo expulsion of secretions would be hampered.) 2. Terpine has been discontinued since 1990's due to lack of efficacy data. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 866(E)	Diphenhydramine+ Terpine+ Ammonium Chloride+ Sodium Chloride+ Menthol	Skymap Pharmaceutical	Diphenhydramine HCl IP 12.5mg+ Terpine Hydrate USP 7.5mg+ Ammonium Chloride IP 125mg+ Sodium Chloride IP 55mg per 5ml syrup	Anti cough	i) Package insert not submitted. ii) Not submitted	For the indication mentioned by the appellant i.e. Broad spectrum antibiotic, this FDC is irrelevant, irrational and hence not recommended. The Subcommittee further noted that the FDC per se is: 1.The FDC per se is pharmacodynamically antagonistic and hence inappropriate. (Ammonium chloride and Sodium citrate are expectorants whereas Diphenhydramine is cough suppressant and soo expulsion of secretions would be hampered.) 2. Terpine has been discontinued since 1990's due to lack of efficacy data. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
162	S.O. 866(E)	Diphenhydramine+ Terpine+ Ammonium Chloride+ Sodium Chloride+ Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 867(E)	Nimesulide+ Paracetamol+ Cetirizine+ Phenylephrine	Akums Drugs	Nimesulide BP 100mg+ Paracetamol IP 325mg+ Cetirizine HCl IP 5mg+ Phenylephrine HCl IP 5mg uncoated table	Relief of nasal and sinus congestion, relief of allergic symptoms of the nose or throat due to upper respiratory tract allergies, relief of sinus pain and headache, adjunct with antibacterial in sinusitis, tonsillitis and otitis media.	i) Indication same as Annexure-A ii) Not Approved	The Subcommittee noted that FDC of Nimesulide+ Levocetirizine was deliberated by SEC (Pulmonary) in its meeting held on 24.09.2014: "The SEC committee examined and opined that the FDC is not rational as Levocetirizine is anti-histaminic whereas Nimesulide is an antipyretic- analgesic and the combination is likely to be misused/overused in situations where single drug is required. Further this FDC is not approved anywhere in the world. Hence the SEC committee did not recommend for its continued marketing in the country." The DTAB Subcommittee concured with the opinion of SEC and opined that the same is applicable to Cetrizine. It further noted that: 1. This FDC is pharmacokinetically incompatible as Cetirizine is given once a day whereas paracetamol is given four times a day. 2. Nimesulide use in the E.U. is limited to ≤15 days due to the risk of hepatotoxicity. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
163	S.O. 867(E)	Nimesulide+ Paracetamol+ Cetirizine+ Phenylephrine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 868(E)	Paracetamol+ Loratadine+ Dextromethorphan+ Pseudoepheridine+ Caffeine	SKN Organics	Paracetamol 650mg+ Loratadine 3.3mg+ Dextromethorphan Hydrobromide 10mg+ Pseudoepheridine HCl 60mg+ Caffeine (Anhydrous) 30mg uncoated tablet	Mild to moderate pain & fever, headache, Chronic cough, nonproductive cough, Temporary relief in nasal congestion associated with upper respiratory allergy, common cold or sinusitis, Temporary relief of sinus congestion & pressure, Seasonal or perennial allergic rhinitis, Chronic idiopathic urticaria, Fever associated with common cold, Fever with nasal congestion and cough, Hay fever with common cold and cough, To get relief from fever, cough, allergic conditions	i) SREYAS TABLET is used for the fast effective temporary relief of the symptoms of cold, flu & fever. Sreyas tablet contain the active ingredients paracetamol, pseudoephedrine hydrochloride, dextromethorphan hydrobromide, loratadine and Caffeine. Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever. Pseudoephedrine hydrochloride belongs to a group of medicines called sympathomimetic decongestants. It works by reducing congestion in the upper respiratory tract including the nose, nasal passages, sinuses and making it easier to breathe. Dextromethorphan is a cough suppressant that acts on the cough centre in the brain to suppress a dry cough. Loratadine is anti histamine, it reduce allergic symptoms. ii) Not submitted	1. Pharmacokinetic incompatibility as loratadine is given once a day whereas other ingredients are given three to four times a day. 2. Dextromethorphan and Loratidine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. Painent population is not well defined. 4. Patients may need only one ingredient and use of this FDC with five ingredients may lead to unnecessary exposure to other ingredients and their side effects. 5. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect claimed by the appellant. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
164	S.O. 868(E)	Paracetamol+ Loratadine+ Dextromethorphan+ Pseudoepheridine+ Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 869(E)	Chlorpheniramine maleate+ Dextromethorphan+ Dextromethorphan+ Guaiphenesin+ Ammonium chloride+ Menthol	-	-	-	-	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, no evidence was found in this regard. The Subcommittee further noted that: 1. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation.. 2. Pharmacodynamically antagonistic and hence inappropriate (Guaiphenesin and Ammonium Chloride are expectorants whereas Chlorpheniramine is anti-histaminic, cough suppressant and anti-cholinergic that dries up secretion and Dextromethorphan is cough suppressant). 3. There is no rationale and evidence to add two anti-tussives and/or two expectorants in an FDC. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. The Combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
165	S.O. 869(E)	Chlorpheniramine maleate+ Dextromethorphan+ Dextromethorphan+ Guaiphenesin+ Ammonium chloride+ Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.** **Further, the Dextromethorphan has been mentioned twice inadvertenly in the notification and hence it should also be amended accordingly.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A			i. Indication as per package insert ii. Marketing anywhere	Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)		
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	NuLife	Chlorpheniramine Maleate IP 4mg+ Ammonium Chloride IP 120mg+ Sodium Citrate IP 50mg per 5ml syrup	For symptomatic treatment of cough.	i)Indications same as Annexure-A ii) Not mentioned	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	Juggat	Chlorpheniramine Maleate IP 2mg+ Ammonium Chloride IP 100mg+ Sodium Citrate IP 50mg per 5ml syrup	It is indicated in cough and cold.	i. Package insert was not submitted. ii. Marketed in Thailand	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	Cipla Ltd.	Chlorpheniramine Maleate 2.5mg+ Ammonium Chloride 125mg+ Sodium Citrate 55mg per 5ml syrup	For the treatment of common cold and cough	Indications same as Annexure-A	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	Alkem	Chlorpheniramine Maleate 2.5mg+ Ammonium Chloride 125mg+ Sodium Citrate 55mg per 5ml syrup	Cough and cold.	i. Indications mentioned in package insert are: For the symptomatic treatment of cough. Ii. Not mentioned	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	GlaxoSmith Kline	Chlorpheniramine Maleate IP 2.5mg+ Ammonium Chloride IP 125mg+ Sodium Citrate IP 55mg per 5ml syrup	For symptomatic treatment of cough	Indications same as Annexure-A	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	Ind Swift	Chlorpheniramine Maleate IP 2.5mg+ Ammonium Chloride IP 125mg+ Sodium Citrate IP 55mg per 5ml syrup	It is used in cough due to allergy and cold.	i. Indication mentioned in Annexure A do not match with package insert. Indications mentioned in package insert are: It is usde for the traetment , control, prevention & improvement of following diseases, conditions and symptoms: cough relief , hypochloremia, metabolioc alkalosis, pain in arthritis, pain in shoulder joint, pain in tendons , pain in muscle strains or sprains , back pain, bruising , runny nose, sneezing, itching, watery eyes caused by allergies, common cold , flu, allergies due to food, acidity, gastric problems and kidney stones ii. Not Submitted	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	Mascot Healthcare	Chlorpheniramine Maleate IP 4mg+ Ammonium Chloride IP 120mg+ Sodium Citrate IP 50mg per 5ml syrup	Cough and cold.	i. Not submitted ii. Not submitted	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	Zaneka Healthcare	Chlorpheniramine Maleate IP 4mg+ Ammonium Chloride IP 120mg+ Sodium Citrate IP 50mg per 5ml syrup	Allergic rhinitis, allergic bronchitis, URTI & LRTI, post nasal drip	i. Not submitted ii. Not submitted	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	Skymap Pharmaceutical	Ammonium Chloride IP 125mg+ Sodium Citrate IP 55mg+ Chlorpheniramine Maleate IP 2.5mg per 5ml syrup	Anti cough	i. Not submitted ii. Not submitted	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	Tirupati Medicare	Chlorpheniramine Maleate IP 2.5mg+ Ammonium Chloride IP 125mg+ Sodium Citrate IP 55mg per 5ml syrup	Treatment of cough	i. Indication mentioned in Annexure A do not match with package insert. Indications mentioned in package insert are: Active ingredients may be combined in various ways according to the perceived needs of patients for multi-symptom relief of common cold or cough symptoms. Triple combinations are commonly marketed with first generation antihistamine, expectorant and mucolytic. This triple combination provides some general benefit in adults. It treats symptomatic relief for cough of varied etiology including that associated with respiratory infections. The first generation antihistamines are commonly used in multi symptom relief medicines as they have a broad pharmacological activity and also act as sedatives, which make them particularly beneficial for cough symptoms. The anti-histamine has been used for over sixty years in multisymptom medicines to control cough ii. Not submitted	The Subcommittee noted that the FDC is pre 1988. Further: 1. The FDC is pharmacodynamically inappropriate: Ammonium chloride and Sodium citrate (Expectorants) increase the mucus secretion in respiratory tract whereas Chlorpheniramine is cough supressant that dries up secretions. 2. The rationale and evidence for combining two expectorants (Ammonium chloride & Sodium citrate) are lacking. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
166	S.O. 870(E)	Chlorpheniramine Maleate+ Ammonium Chloride+ Sodium Citrate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 871(E)	Cetirizine + Phenylephrine + Paracetamol+ Zinc Gluconate	Hema Laboratories	Cetirizine HCL IP 2.5mg+ Paracetamol IP 125mg+ Phenylephrine HCl IP 2.5mg+ Zinc Gluconate USP 26.14mg eq. to elemental Zinc 3.75mg per 5ml syrup	Symptomatic treatment of common cold, flu and allergic rhinitis.	i) Indication same as Annexure-A ii) Not submitted	1. There is pharmacokinetic incompatibility: Paracetamol is given four times a day whereas Cetirizine is given once a day. 2. Paracetamol is not required in allergic rhinitis and common cold as fever, headache, myalgia are not always associated with them. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 871(E)	Cetirizine + Phenylephrine + Paracetamol+ Zinc Gluconate	Hema Laboratories	Cetirizine HCL IP 2.5mg+ Paracetamol IP 250mg+ Phenylephrine HCl IP 5mg+ Zinc Gluconate USP 26.14mg eq. to elemental Zinc 3.75mg per 5ml suspension	Symptomatic treatment of common cold, flu and allergic rhinitis.	i) Indication same as Annexure-A ii) Not submitted	1. There is pharmacokinetic incompatibility: Paracetamol is given four times a day whereas Cetirizine is given once a day. 2. Paracetamol is not required in allergic rhinitis and common cold as fever, headache, myalgia are not always associated with them. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 871(E)	Cetirizine + Phenylephrine + Paracetamol+ Zinc Gluconate	Mepromax Lifesciences	Cetirizine HCL IP 5mg+ Paracetamol IP 325mg+ Phenylephrine HCl IP 5mg+ Zinc Gluconate USP 52.28mg eq. to elemental Zinc 7.5mg uncoated tablet	Symptomatic treatment of common cold, flu and allergic rhinitis.	i) Indication same as Annexure-A ii) Not submitted	1. There is pharmacokinetic incompatibilit : Paracetamol is given four times a day whereas Cetirizine is given once a day. 2. Paracetamol is not required in allergic rhinitis and common cold as fever, headache, myalgia are not always associated with them. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
167	S.O. 871(E)	Cetirizine + Phenylephrine + Paracetamol+ Zinc Gluconate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 872(E)	Ambroxol+ Guaiphenesin+ Ammonium Chloride+ Phenylephrine+ Chlorpheniramine Maleate+ Menthol	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate (Ambroxol, Guaiphenesin and Ammonium chloride are mucolytic and expectorant whereas Chlorpheniramine is anti-histaminic cough suppressant and anti-cholinergic and dries up secretion). 2. There is no rationale or evidence to add 2 expectorants in an FDC. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5.The Combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
168	S.O. 872(E)	Ambroxol+ Guaiphenesin+ Ammonium Chloride+ Phenylephrine+ Chlorpheniramine Maleate+	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 873(E)	Dextromethorphen+ Bromhexine + Chlorpheniramine maleate+ Guaiphenesin	Akums Drugs	Dextromethorphen HCl IP 10mg+ Bromhexine HCl IP 8mg+ Chlorpheniramine maleate IP 2mg+ Guaiphenesin IP 100mg uncoated tablet	Secretolytic therapy in acute and chronic bronchopulmonary disease associated with abnormal mucus secretion and impaired mucus secretion and impaired mucus transport. Reduces the viscosity of uninfected bronchial secretions in bronchial asthma, chronic	i. Indication mentioned in Annexure A do not match with package insert. Indications mentioned in package insert includes pulmonary emphysema, cystic fibrosis, minor throat/ bronchial irritation in common cold and inhaled irritants. Ii. Not Submitted	1. Pharmacodynamically antagonistic and hence inappropriate: As Dextromethorphan and Chlorpheniramine supress cough reflex, expulsion of secretion would be hampered and hence mucolytic/ expectorant (Bromhexine and Guaiphenesin) should not be combined with them. 2.Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3.Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 873(E)	Dextromethorphen+ Bromhexine + Chlorpheniramine maleate+ Guaiphenesin	Mascot Healthcare	Dextromethorphan Hbr IP 10mg+ Guaiphenesin IP 100mg+ Bromhexine Hcl IP 8mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Expectorant and mucolytic, Bronchitis, Thick or sticky	i. Indication mentioned in Annexure A do not match with package insert. Indications mentioned in package insert includes cough , Rhinitis and bronchitis. ii. Not submitted	1. Pharmacodynamically antagonistic and hence inappropriate: As Dextromethorphan and Chlorpheniramine supress cough reflex, expulsion of secretion would be hampered and hence mucolytic/ expectorant (Bromhexine and Guaiphenesin) should not be combined with them. 2.Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3.Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibiton Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 873(E)	Dextromethorphen+ Bromhexine + Chlorpheniramine maleate+ Guaiphenesin	HAB Pharmaceuticals	Dextromethophen HBr BP 10mg+ bromhexine HCl BP 8mg+ chlorpheniramine maleate USP 2mg+ guaiphenesin BP 100mg uncoated tablet	For symptomatic relief of cough and cold. This is a combination of four medicines: Guaifenesin, bromhexine, chlorpheniramine and dextromethorphan which relieve dry cough. Guaifenesin is an expectorant which decreases the stickiness of mucus (phlegm) and helps in its removal from the airways. Bromhexine is a mucolytic which thins and loosens mucus (phlegm), making it easier to cough out. Chlorpheniramine is an antiallergic which relieves allergy symptoms like runny nose, watery eyes and sneezing. Dextromethorphan is a cough suppressant that relieves cough by reducing the activity of cough centre in the brain.	i. Not Submitted ii. Not Submitted	1. Pharmacodynamically antagonistic and hence inappropriate: As Dextromethorphan and Chlorpheniramine supress cough reflex, expulsion of secretion would be hampered and hence mucolytic/ expectorant (Bromhexine and Guaiphenesin) should not be combined with them. 2.Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3.Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 873(E)	Dextromethorphen+ Bromhexine + Chlorpheniramine maleate+ Guaiphenesin	Skymap Pharmaceutical	Dextromethophen HBr BP 10mg+ bromhexine HCl IP 8mg+ chlorpheniramine maleate IP 2mg+ guaiphenesin BP 100mg uncoated tablet	Anti-cough	i. Not Submitted ii. Not Submitted	1. Pharmacodynamically antagonistic and hence inappropriate: As Dextromethorphan and Chlorpheniramine supress cough reflex, expulsion of secretion would be hampered and hence mucolytic/ expectorant (Bromhexine and Guaiphenesin) should not be combined with them. 2.Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3.Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 873(E)	Dextromethorphen+ Bromhexine + Chlorpheniramine maleate+ Guaiphenesin	Skymap Pharmaceutical	Dextromethophen HBr BP 10mg+ Bromhexine HCl IP 4mg+ Chlorpheniramine maleate IP 2mg+ Guaiphenesin BP 100mg uncoated tablet	Anti-cough	i. Not Submitted ii. Not Submitted	1. Pharmacodynamically antagonistic and hence inappropriate: As Dextromethorphan and Chlorpheniramine supress cough reflex, expulsion of secretion would be hampered and hence mucolytic/ expectorant (Bromhexine and Guaiphenesin) should not be combined with them. 2.Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3.Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 873(E)	Dextromethorphen+ Bromhexine + Chlorpheniramine maleate+ Guaiphenesin	DM Pharma	Dextromethophen HBr BP 10mg+ Bromhexine HCl IP 8mg+ Chlorpheniramine maleate IP 2mg+ Guaiphenesin BP 100mg uncoated tablet	Cough and cold, allergic rhinitis.	i) Same as Annexure A ii) Not submitted	1. Pharmacodynamically antagonistic and hence inappropriate: As Dextromethorphan and Chlorpheniramine supress cough reflex, expulsion of secretion would be hampered and hence mucolytic/ expectorant (Bromhexine and Guaiphenesin) should not be combined with them. 2.Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3.Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
169	S.O. 873(E)	Dextromethorphen+ Bromhexine + Chlorpheniramine maleate+ Guaiphenesin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 874(E)	Levocetirizine+ Ambroxol+ Phenylephrine + Guaiphenesin	Akums Drugs	Levocetirizine+ Ambroxol+ Phenylephrine+ Guaiphenesin film coated tablet	It is indicated for cold and decongestant	i) Pacakage insert has not submitted. ii) Not submitted	1. Pharmacokinetic incompatibility: Guaiphensin is given 4 times a day whereas Levocetirizine is administered onco a day). 2. There is no definitive evidence of Ambroxol in common cold (and not recommended in guidelines). 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 874(E)	Levocetirizine+ Ambroxol+ Phenylephrine + Guaiphenesin	Skymap Pharmaceutical	Levocetirizine Dihydrochloride IP 0.8mg+ Ambroxol HCl IP 15mg+ Phenylephrine HCl IP 5mg+ Guaiphenesin IP 50mg per 5ml syrup	Anti-cough	i)Package insert has not submitted. ii) Not submitted	1. Pharmacokinetic incompatibility: Guaiphensin is given 4 times a day whereas Levocetirizine is administered once a day). 2. There is no definitive evidence of Ambroxol in common cold (and not recommended in guidelines). 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 874(E)	Levocetirizine+ Ambroxol+ Phenylephrine + Guaiphenesin	Tirupati Medicare	Levocetirizine Dihydrochloride IP 0.8mg+ Ambroxol HCl IP 15mg+ Phenylephrine HCl IP 5mg+ Guaiphenesin IP 50mg per 5ml syrup	Treatment of cough	i)Indications mentioned in annxeure-A was differ form the package insert. Package insert includes cough assocaited with nasal congestion as in respiratory tarct infections /allergies. ii) Not submitted	1. Pharmacokinetic incompatibility: Guaiphensin is given 4 times a day whereas Levocetirizine is administered once a day). 2. There is no definitive evidence of Ambroxol in common cold (and not recommended in guidelines). 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 874(E)	Levocetirizine+ Ambroxol+ Phenylephrine + Guaiphenesin	Centaur Pharmaceuticals	Levocetirizine Dihydrochloride IP 0.8mg+ Ambroxol HCl IP 15mg+ Phenylephrine HCl IP 5mg+ Guaiphenesin IP 50mg per 5ml syrup	In the treatment of cold associated with cough	i) Indication same as Annexure-A ii) Not submitted	1. Pharmacokinetic incompatibility: Guaiphensin is given 4 times a day whereas Levocetirizine is administered once a day). 2. There is no definitive evidence of Ambroxol in common cold (and not recommended in guidelines). 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 874(E)	Levocetirizine+ Ambroxol+ Phenylephrine + Guaiphenesin	Centaur Pharmaceuticals	Levocetirizine Dihydrochloride IP 0.8mg+ Ambroxol HCl IP 15mg+ Phenylephrine HCl IP 5mg+ Guaiphenesin IP 50mg per 5ml syrup	Cough associated with nasal congestion, as in respiratory tract infection/ allergies.	i) Not submitted ii) As per firm, this FDC is marketed in India.	1. Pharmacokinetic incompatibility: Guaiphensin is given 4 times a day whereas Levocetirizine is administered once a day). 2. There is no definitive evidence of Ambroxol in common cold (and not recommended in guidelines). 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
170	S.O. 874(E)	Levocetirizine+ Ambroxol+ Phenylephrine + Guaiphenesin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 875(E)	Dextromethorphan+ Chlorpheniramine+ Chlorpheniramine maleate	-	-	-	-	The Subcommittee noted that for S.O. 875 (E), Dextromethorphan+ Chlorpheniramine+ Chlorpheinramine Maleate are stated as ingredients and that there is no product of this description.
171	S.O. 875(E)	Dextromethorphan+ Chlorpheniramine+ Chlorpheniramine maleate	The subcommittee noted that for S.O. 875 (E), Dextromethorphan+ Chlorpheniramine+ Chlorpheinramine Maleate are stated as ingredients and that there is no product of this description. Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 876(E)	Cetirizine+ Ambroxol+ Guaiphenesin+ Ammonium chloride+ Phenylephrine+ Menthol	Horizon Bioceuticals	Cetirizine HCl IP 2.5mg+ ambroxol HCl IP 30mg+ Guaiphenesin IP 50mg+ ammonium chloride IP 100mg+ phenylephrine 5mg+ menthol 1mg per 5ml syrup	Cough & cold	i. Indication mentioned in package insert do not match as above. Package insert includes Cold assocaited with cough. Relief of allergic symptoms of the nose or throat due to upper respiratory tract allergies. Relief of sinus pain and headache. Adjunct with antibacterials in snusitis , tonislitis and otitis media. ii. Not submitted	1. Pharmacokinetically incompatible: Cetirizineis to be given once a day whereas other ingredients are given four times a day. 2. There is no rationale or evidence to add two expectorants in an FDC. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4.The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 876(E)	Cetirizine+ Ambroxol+ Guaiphenesin+ Ammonium chloride+ Phenylephrine+ Menthol	Varav Biogenesis	Cetirizine HCl IP 2.5mg+ ambroxol HCl IP 30mg+ Guaiphenesin IP 50mg+ ammonium chloride IP 100mg+ phenylephrine 5mg+ menthol 1mg per 5ml syrup	Anti-histaminic, Anti-tussive and expectorant cough mixture	i. Indication mentioned in package insert do not match as above. Package insert includes combination relieves congestion, dries a runny nose and post nasal drip and thin mucus to relief. ii. Not submitted	1. Pharmacokinetically incompatible: Cetirizineis to be given once a day whereas other ingredients are given four times a day. 2. There is no rationale or evidence to add two expectorants in an FDC. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4.The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
172	S.O. 876(E)	Cetirizine+ Ambroxol+ Guaiphenesin+ Ammonium chloride+ Phenylephrine+ Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 877(E)	Chlorpheniramine+ Phenylephrine+ Caffeine	-	-	-	-	1. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
173	S.O. 877(E)	Chlorpheniramine+ Phenylephrine+ Caffeine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 878(E)	Dextromethorphan+ Triprolidine+ Phenylephrine	Glenmark Pharmaceuticals	Dextromethorphan HBr 10mg+ Triprolidine HCl 1.25mg+ Phenylephrine HCl 5.0mg per 5ml syup	Temporary relief of cough and upper respiratory tract symptoms including nasal congestion associated with common cold.	i. Indication same as Annexure-A ii. Not submitted	1. Dextromethorphan and Triprolidine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. 4. The comments given by the appellant were noted. However, it was observed that the evidence of combining anti tussive , decongestant & anti-histaminic, lacks consistency in beneficial treatment outcomes. There is no sound scientific/ clinical evidence/ justification for the FDC.
174	S.O. 878(E)	Dextromethorphan+ Triprolidine+ Phenylephrine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 879(E)	Terpin hydrate+ Dextromethorphan+ Menthol	Alembic Pharmaceuticals	Terpin hydrate USP 10mg+ Dextromethorphan Hbr IP 10mg+ Menthol IP 3.75mg per 5ml syrupenthol	Symptomatic treatment of non productive cough	i. Indication same as annexuer-A ii. Not submitted	1. Pharmacodynamically antagonistic and hence inappropriate: Terpine is an expectorant while Dextromethorphan is cough suppressant and so expulsion of the secretions is hampered. 2. Marketing of Terpin hydrate has been discontinued since 1990 due to lack of data regarding efficacy. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
175	S.O. 879(E)	Terpin hydrate+ Dextromethorphan+ Menthol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 880(E)	Dextromethorphan+ Phenylephrine+ Zinc Gluconate+ Menthol	-	-	-	-	1. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and there side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
176	S.O. 880(E)	Dextromethorphan+ Phenylephrine+ Zinc Gluconate+ Menthol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of Ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 881(E)	Chlorpheniramine+ Codeine+ Sodium citarte+ Menthol syrup	-	-	-	-	1. Codeine and Chlorpheniramine, both cause sedation and drowsiness. Their combination may lead to excessive sedation. It is therefore inappropriate to combine these two drugs in FDC. 2. There is also a risk of abuse potential in view of codeine being one of the ingredients. 3. Pharmacodynamically antagonistic and hence inappropriate: Sodium citrate is an expectorant while Chlorpheniramine and Codeine are cough supressants and hamper expulsion of secretions. In addition, Chlorpheniramine dries up the secretions while Sodium citrate increases secretions. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
177	S.O. 881(E)	Chlorpheniramine+ Codeine+ Sodium citarte+ Menthol syrup	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 882(E)	Enrofloxacin+ Bromhexin	-	-	-	-	The Subcommittee noted that FDC of Enrofloxacin 200 mg+ Bromhexine HCl IP 15mg oral solution is approved by DCGI as a "Veterinary product". Further: 1. Enrofloxacin is not approved for human use. There is no sound scientific/ clinical evidence/ justification for the FDC for use in human beings.
178	S.O. 882(E)	Enrofloxacin+ Bromhexin	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 883(E)	Bromhexine + Dextromethorphan + Phenylephrine + Menthol	Mascot Healthcare	Dextromethorphan Hbr IP 5mg+ Bromhexine Hcl IP 4mg+ Phenylephrine HCL IP 5mg+ Menthol IP 2.5mg per 5ml syrup	Dry Cough, cold and nasal congestion.	i. Indication mentioned in package insert do not match with Annexure A. Package insert includes cough , Rhinitis and bronchitis. ii. Not submitted	1. Pharmacodynamically antagonistic and hence inappropriate: Bromhexine (Mucolytic/Expectorant) increases the mucus secretion in respiratory tract whereas Dextromethorphan (an anti-tussive) suppresses cough and hampers expulsion of secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
179	S.O. 883(E)	Bromhexine + Dextromethorphan + Phenylephrine + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 884(E)	Levofloxacin+ Bromhexine	-	-	-	-	The DTAB Subcommittee noted that the FDC of Gemifloxacin with Ambroxol was deliberated by SEC (Pulmonary) in its meeting held on 23-12-2015: "The proposal of continued marketing of Gemifloxacin+ Ambroxol was deliberated in current scenario. The Committee opined that Ambroxol being a mucolytic agent does not have any added advantage in the antimicrobial activity. Therefore the Committee considered the FDC as irrational in current scenario and did not recommend for its continued marketing." The DTAB Subcommittee concured with the opinion of SEC as the same comment applies for FDC, Levofloxacin+ Bromhexine. The Subcommittee noted further that: 1. The FDC ispharmacokinetically incompatible: Levofloxacin is given once a day whereas Bromhexine is given thrice a day. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
180	S.O. 884(E)	Levofloxacin+ Bromhexine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 885(E)	Levocetirizine + Ranitidine	-	-	-	-	1. Pharmacodynamically inappropriate: Indications for individual ingredients are different. Ranitidine is used in peptic ulcer diseases but Levocetirizine has no role. 2. The current evidence does not support use of H2 antagonist (Ranitidine) with H1 anti histamines (Levocetirizine) as FDC in chronic urticaria. 3. Use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. 4. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
181	S.O. 885(E)	Levocetirizine + Ranitidine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 886(E)	Levocetirizine+ Phenylephrine+ Ambroxol+ Guaiphenesin+ Paracetamol	-	-	-	-	1. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 2. Paracetamol is not always required in nasal congestion and common cold as fever is not always associated with them. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. The FDC ispharmacokinetically incompatible: Levocetirizine is given once a day whereas other ingredients are given four times a day. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
182	S.O. 886(E)	Levocetirizine+ Phenylephrine+ Ambroxol+ Guaiphenesin+ Paracetamol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 887(E)	Cetirizine+ Dextromethorphan+ Phenylephrine+ Zinc gluconate+ Paracetamol+ Menthol	-	-	-	-	1. Dextromethorphan and Cetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 2. The FDC is pharmacokinetically incompatible: Cetirizine is given once a day whereas other ingredients are given four times a day. 3. Patients may not need all the six ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
183	S.O. 887(E)	Cetirizine+ Dextromethorphan+ Phenylephrine+ Zinc gluconate+ Paracetamol+	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 888(E)	Paracetamol+ Pseudoephedrine + Dextromethorphan+ Cetirizine	Skan Research	Paracetamol IP 500mg+ Pseudoephedrine HCl IP 60mg+ Dextromethorphan HBr IP 10mg+ Cetirizine HCl IP 5mg per uncaoted tablet	Mild to moderate pain & fever, headache, Chronic cough, nonproductive cough, Temporary relief in nasal congestion associated with upper respiratory allergy, common cold or sinusitis, Temporary relief of sinus congestion & pressure, Seasonal or perennial allergic rhinitis, chronic idiopathic urticaria, Fever associated with common cold, Fever with nasal congestion and cough, Hay fever with common cold and cough, To get relief from fever, cough, allergic conditions.	i. Indications mentioned in annxeure-A is different form the package insert.Additional indication mentioned in package insert are: As an adjuct with anti bacterial in sinusitis , tonislitis and otitis media. ii. Not submitted	1. Pharmacokinetic incompatibility as Cetirizine is given once a day whereas other ingredients are given three/ four times a day. 2. Dextromethorphan and Cetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 3. Patients may need only one ingredient and use of this PDC may lead to unnecessary exposure to other ingredients. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 888(E)	Paracetamol+ Pseudoephedrine + Dextromethorphan+ Cetirizine	Skan Research	Paracetamol IP 250mg+ Pseudoephedrine HCl IP 15mg+ Dextromethorphan HBr IP 5mg+ Cetirizine HCl IP 2.5mg per 5ml syrup	Mild to moderate pain & fever, head ache,Chronic cough, nonproductive cough, Temporary relief in nasal congestion associated with upper respiratory allergy, common cold or sinusitis, Temporary relief of sinus congestion & pressure, Seasonal or perennial allergic rhinitis, Chronic idiopathic urticaria, Fever associated with common cold, Fever with nasal congestion and cough, Hay fever with common cold and cough, To get relief from fever, cough, allergic conditions	i.Indication not mentioned in package insert ii. Not submitted	1. Pharmacokinetic incompatibility as Cetirizine is given once a day whereas other ingredients are given three/ four times a day. 2. Dextromethorphan and Cetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation.. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
184	S.O. 888(E)	Paracetamol+ Pseudoephedrine + Dextromethorphan+ Cetirizine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 889(E)	Diphenhydramine+ Guaiphenesin+ Ammonium chloride+ Bromhexine	Varav Biogenesis	Each 5ml syrup (sugarfree) contains: Diphenhydramine HCl 8mg Ammonium chloride IP 100mg Bromhexine Hydrochloride 4mg Guaiphenesin 50mg Menthol IP 1mg	Anti-tussive and expectorant cough mixture	i. Indication different from Annexure A. Indication in package insert is: Combination relieves congestion, dries a runny nose and post nasal drip and thins mucus to relief coughing ii. NA	1. Pharmacodynamically antagonistic and hence inappropriate: Guaiphenesin, Ammonium chloride & Bromhexine are expectorants/ mucolytic agents whereas Diphenhydramineis a cough supressant and hampers expulsion of secretions. Moreover, it dries up secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
185	S.O. 889(E)	Diphenhydramine+ Guaiphenesin+ Ammonium chloride+ Bromhexine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 890(E)	Chlorpheniramine + Dextromethorphan + Phenylephrine+ Paracetamol	Acron	Chlorpheniramine malcate IP 2mg+ Dextromethorphan HBr IP 10mg+ Phenylephrine HCl IP 5mg+ Paracetamol IP 250mg oral suspension	Indicated for relief of symptoms assocaited with colds and influenzasuch as nasal congestion, sniffing, haedache, minor aches and pains.	i. Package insert not submitted. Ii. Not approved	1. Pharmacokinetically incompatible FDC: Paracetamol is to be given 4 times a day whereas Chlorpheniramine is to be given twice a day. 2. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may need all the ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 890(E)	Chlorpheniramine + Dextromethorphan + Phenylephrine+ Paracetamol	Skymap Pharmaceutical	Chlorpheniramine Maleate IP 1mg+ Dextromethorphan Hbr IP 5mg+ Phenylephrine Hcl IP 5mg+ Paracetamol IP 250mg per 5ml syrup	Anti-cough	i. Not Submitted ii. Not Submitted	1. Pharmacokinetically incompatible FDC: Paracetamol is to be given 4 times a day whereas Chlorpheniramine is to be given twice a day. 2. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may need all the ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 890(E)	Chlorpheniramine + Dextromethorphan + Phenylephrine+ Paracetamol	Varav Biogenesis	Chlorpheniramine Maleate IP 2mg+ Dextromethorphan Hbr IP 5mg+ Phenylephrine Hcl IP 5mg+ Paracetamol IP 250mg per 5ml suspension	Cold and cough Suspension.	i. Indications mentioned in package insert do not match as above. Package insert mentions additional indications of relief from allergy, symptoms of congestion of nose and throat due to respiratory tract allergies, relief from headache, sinus pain and adjunct with anti bacterial in sinusitis, tonsillitis and otitis media. ii. Not approved	1. Pharmacokinetically incompatible FDC: Paracetamol is to be given 4 times a day whereas Chlorpheniramine is to be given twice a day. 2. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may need all the ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 890(E)	Chlorpheniramine + Dextromethorphan + Phenylephrine+ Paracetamol	Akums Drugs	Each 5 ml contains:- Paracetamol IP 125 mg+ Dextromethorphan Hydrobromide IP 5 mg+ Chlorpheniramine Maleate IP 2 mg+ Phenylephrine Hydrochloride BP 5mg	It is indicated for cough and fever as in respiratory tract infections / allergies in children aged 6 years and above	i. Same as Annexure A ii. Not approved	1. Pharmacokinetically incompatible FDC: Paracetamol is to be given 4 times a day whereas Chlorpheniramine is to be given twice a day. 2. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may need all the ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 890(E)	Chlorpheniramine + Dextromethorphan + Phenylephrine+ Paracetamol	DM Pharma	Chlorpheniramine Maleate IP 2mg+ Dextromethorphan HBr IP 5mg+ Phenylephrine HCl IP 5mg+ Paracetamol IP 250mg per 5ml syrup	Allergic rhinitis, fever and headache associated with cold., nasal decongestion. (as submitted)	i) same as Annexure A ii) Not submitted	1. Pharmacokinetically incompatible FDC: Paracetamol is to be given 4 times a day whereas Chlorpheniramine is to be given twice a day. 2. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may need all the ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 890(E)	Chlorpheniramine + Dextromethorphan + Phenylephrine+ Paracetamol	Akums	Chlorpheniramine Maleate IP 2mg+ Dextromethorphan Hbr IP 5mg+ Phenylephrine Hcl IP 5mg+ Paracetamol IP 125mg per 5ml syrup	It is indicated for cough associated with nasal congestion as in respiratory tract infections/ Allergies	i. Not Submitted ii. Not Submitted	1. Pharmacokinetically incompatible FDC: Paracetamol is to be given 4 times a day whereas Chlorpheniramine is to be given twice a day. 2. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may need all the ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
186	S.O. 890(E)	Chlorpheniramine + Dextromethorphan + Phenylephrine+ Paracetamol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 891(E)	Dextromethorphen+ Promethazine	-	-	-	-	1. Dextromethorphan and Promethazine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 2. There is no rationale for combining two anti-tussives in n FDC. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
187	S.O. 891(E)	Dextromethorphen+ Promethazine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 892(E)	Diethylcabamazine+ Cetirizine+ Guaiphenesin	-	-	-	-	1. Pharmacodyanmically inappropriate: The indications of the 3 ingredients are different. 2. Pharmacokinetically incompatible: Guaifenesin is given four tims a day whereas Cetirizine and Diethylcarbamazine are given once a day. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
188	S.O. 892(E)	Diethylcabamazine+ Cetirizine+ Guaiphenesin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 893(E)	Pseudoephedrine+ Dextromethorphan+ Cetirizine	Skan Research	Pseudoephedrine HCl 60mg+ Dextromethorphan HBr 10mg+ Cetirizine HCl 5mg uncoated tablet	Chronic cough non-productive cough, temporary relief in nasal congestion associated with upper respiratory allergy, common cold or sinusitis, temporary relief of sinus congestion and pressure, seasonal or perennial allergic rhinitis chronic idiopathic urticarial, cold, nasal congestion and cough, to get relief from nasal congestion cough allergic conditions.	i. Indication mentioned in package insert do not match as above. Package insert includes a adjunct with antibacterialin sinusitis , tonsilitis and otitis media and relief of sinus pain and headache. ii. Not submitted	1. Dextromethorphan and Cetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 2. Dextromethorphan is given four times a day while Cetirizine is given once a day. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
189	S.O. 893(E)	Pseudoephedrine+ Dextromethorphan+ Cetirizine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 894(E)	Chlorpheniramine + Phenylephrine + Dextromethorphan + Menthol	Laborate Pharmaceutical	Chlorpheniramine Maleate IP 2mg+ Dextromethorphan Hydrobromide IP 10mg+ Pheylephrine HCl IP 5mg+ Menthol 0.75mg per 5ml syrup	Relief from coughs and upper respiratory tract symptoms, including nasal congestion, associated with allergy or common cold.	i.Indications same as Annexure-A ii. Not submitted	The Subcommittee noted that FDC of Chlorpheniramine Maleate IP 2mg+ Dextromethorphan Hydrobromide IP 10mg+ Phenylephrine Hydrochloride IP 5mg Softgel Capsule is approved by DCGI. Further, the Subcommittee also noted that FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine is also approved by DCGI based on Kokate committee. The Subcommittee further noted that SO no. 894 i.e. FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine+ Menthol is already reviewed by Kokate committee during its meeting held on 26th and 27th May 2016 wherein the Kokate committee mentioned that this FDC was declared irrational inadvertently and the Kokate committee finally after review considered this FDC as 'rational'. The comments of the DTAB Subcommittee are as under: 1. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 894(E)	Chlorpheniramine + Phenylephrine + Dextromethorphan + Menthol	Ind-Swift Ltd.	Chlorpheniramine Maleate IP 2mg+ Dextromethorphan Hydrobromide IP10mg+ Pheylephrine HCl IP 5mg+ Menthol 1.5mg per 5ml syrup	Helps to reduce coughing and relieves persistent dry irritant coughs, treats runny nose (sneezing), itchy and watery eyes. For relieving of symptoms due to the common cold, hay fever or other upper respiratory allergies.	i. Package insert not submitted. ii. Not Submitted	The Subcommittee noted that FDC of Chlorpheniramine Maleate IP 2mg+ Dextromethorphan Hydrobromide IP 10mg+ Phenylephrine Hydrochloride IP 5mg Softgel Capsule is approved by DCGI. Further, the Subcommittee also noted that FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine is also approved by DCGI based on Kokate committee. The Subcommittee further noted that SO no. 894 i.e. FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine+ Menthol is already reviewed by Kokate committee during its meeting held on 26th and 27th May 2016 wherein the Kokate committee mentioned that this FDC was declared irrational inadvertently and the Kokate committee finally after review considered this FDC as 'rational'. The comments of the DTAB Subcommittee are as under: 1. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 894(E)	Chlorpheniramine + Phenylephrine + Dextromethorphan + Menthol	Mascot Healthcare	Dextromethorphan Hbr IP 10mg+ Chlorpheniramine Maleate IP 2mg+ Phenylephrine HCl IP 5mg+ Menthol IP 1mg per 5ml syrup	Cough, Rhinitis and Bronchitis	i. Indication same as Annexure-A ii. Not submitted	The Subcommittee noted that FDC of Chlorpheniramine Maleate IP 2mg+ Dextromethorphan Hydrobromide IP 10mg+ Phenylephrine Hydrochloride IP 5mg Softgel Capsule is approved by DCGI. Further, the Subcommittee also noted that FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine is also approved by DCGI based on Kokate committee. The Subcommittee further noted that SO no. 894 i.e. FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine+ Menthol is already reviewed by Kokate committee during its meeting held on 26th and 27th May 2016 wherein the Kokate committee mentioned that this FDC was declared irrational inadvertently and the Kokate committee finally after review considered this FDC as 'rational'. The comments of the DTAB Subcommittee are as under: 1. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

me

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 894(E)	Chlorpheniramine + Phenylephrine + Dextromethorphan + Menthol	Meridian Medicare	Chlorpheniramine 2mg+ Phenylephrine 5mg+ Dextromethorphan 10mg+ Menthol 5mg syrup	Expectorant , Protective cough	I) Not submitted ii) Not submitted	The Subcommittee noted that FDC of Chlorpheniramine Maleate IP 2mg+ Dextromethorphan Hydrobromide IP 10mg+ Phenylephrine Hydrochloride IP 5mg Softgel Capsule is approved by DCGI. Further, the Subcommittee also noted that FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine is also approved by DCGI based on Kokate committee. The Subcommittee further noted that SO no. 894 i.e. FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine+ Menthol is already reviewed by Kokate committee during its meeting held on 26th and 27th May 2016 wherein the Kokate committee mentioned that this FDC was declared irrational inadvertently and the Kokate committee finally after review considered this FDC as 'rational'. The comments of the DTAB Subcommittee are as under: 1. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 894(E)	Chlorpheniramine + Phenylephrine + Dextromethorphan + Menthol	Franklin Labor	Dextromethorphan HBr IP 15mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine maleate IP 2mg per 5ml syrup	Not submitted	i) Not submitted ii) Not submitted	The Subcommittee noted that FDC of Chlorpheniramine Maleate IP 2mg+ Dextromethorphan Hydrobromide IP 10mg+ Phenylephrine Hydrochloride IP 5mg Softgel Capsule is approved by DCGI. Further, the Subcommittee also noted that FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine is also approved by DCGI based on Kokate committee. The Subcommittee further noted that SO no. 894 i.e. FDC of Dextromethorphan+ Chlorpheniramine+ Phenylephrine+ Menthol is already reviewed by Kokate committee during its meeting held on 26th and 27th May 2016 wherein the Kokate committee mentioned that this FDC was declared irrational inadvertently and the Kokate committee finally after review considered this FDC as 'rational'. The comments of the DTAB Subcommittee are as under: 1. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
190	S.O. 894(E)	Chlorpheniramine + Phenylephrine + Dextromethorphan + Menthol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

ME

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 895(E)	Ambroxol + Terbutaline+ Dextromethorphan	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate: Ambroxol is mucolytic whereas Dextromethorphan is cough supressant and hampers expulsion of secretions. 2. This combination is not as per standard therapeutic guidelines. 3. As per guidelines, there is no role for mucolytic in asthma. 4. Mucolytic (Ambroxol) alongwith anti-asthmatic drug is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drug (Terbutaline) and its adverse effects. There is no scientific/ clinical evidence/ justification submitted by the company for the FDC.
191	S.O. 895(E)	Ambroxol + Terbutaline+ Dextromethorphan	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 896(E)	Dextromethorphan + Chlorpheniramine + Guaiphenesin	Coral Laboratories	Dextromethorphan Hbr 10mg + Chlorpheniramine Maleate IP 4mg + Guaiphenesin 100mg per 5ml syrup	Dry cough	i. Indication is not clearly stated in product insert. ii. Not approved	1. Pharmacodynamically antagonistic and hence inappropriate (Guaiphenesin is mucolytic/ expectorant whereas Dextromethorphan is cough suppressant, Chlorpheniramine dries up secretion and also supresses cough). 2. Dextromethorphan and chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
192	S.O. 896(E)	Dextromethorphan + Chlorpheniramine + Guaiphenesin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

ORE

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 897(E)	Terbutaline + Bromhexine + Guaiphenesin+ Dextromethorphan	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate: Bromhexine is a mucolytic and Guaiphenesin is an expectorant; both increase the secretions whereas Dextromethorphan supresses cough, which hampers the expulsion of secretions. 2. As per guidelines, there is no role for mucolytic in asthma. 3. Mucolytic (Bromhexine) alongwith anti-asthmatic drug is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drug (Terbutaline) and its adverse effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
193	S.O. 897(E)	**Terbutaline + Bromhexine + Guaiphenesin+ Dextromethorphan**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

ME

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 898(E)	Dextromethorphan + Tripolidine + Phenylephirine	-	-	-	-	1. Dextromethorphan and Triprolidine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
194	S.O. 898(E)	Dextromethorphan + Tripolidine + Phenylephirine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 899(E)	Paracetamol + Dextromethorphan + Chlorpheniramine	-	-	-	-	1. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
195	S.O. 899(E)	**Paracetamol + Dextromethorphan + Chlorpheniramine**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 900(E)	Pholcodine+ Phenylephrine + Promethazine	Acron	Pholcodine IP 1.5mg+ Phenylephrine HCl IP 2.5mg+ Promethazine HCl IP 1.5mg oral syrup	Indicated for symptomatic treatment of dry and irritating cough.	i. Not Submitted ii. Not approved	1. Pholcodine and Promethazine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
196	S.O. 900(E)	Pholcodine+ Phenylephrine + Promethazine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 901(E)	Codeine + Levocetirizine + Menthol	Windlas Biotech	Codeine Phosphate IP 10mg+ Levocetirizine HCl IP 1.67mg+ Menthol IP 0.1mg per 5ml syrup	For the treatment of Allergic condition	i. Same as annexure-A ii. Not submitted	1. Pharmacokinetically incompatible as Levocetirizine is given once a day while codeine is given 3 – 4 times a day. 2. Codeine and Levocetirizine both cause sedation and drowsiness . It is inappropriate to combine these two drugs in FDC. 3. There is also a risk of abuse potential. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5.The target population is not properly defined as the indication mentioned is "In the treatment of Allergic conditions". 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
197	S.O. 901(E)	Codeine + Levocetirizine + Menthol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 902(E)	Dextromethorphan + Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate: Mucolytic (Ambroxol) and expectorant (Guaiphenesin), which increase respiratory secretions should not be combined with cough suppressants (Dextromethorphan and Chlorpheniramine), which hamper expulsion of secretions. 2. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
198	S.O. 902(E)	**Dextromethorphan + Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 903(E)	Cetirizine + Phenylephrine + Dextromethorphan + Menthol	Tablets (I) Ltd.	Cetirizine HCL IP 5mg+ Phenylephrine HCL IP 5mg+ Dextromethorphan HCL IP 10mg+ Menthol IP 1.5mg per 5ml syrup	Dry Cough due to post nasal drip (As informed by company during presentation)	i. Same as annexure-A ii. Not approved	1.Phamacokinetically incompatible: Dextromethorphan is given 3-4 times a day whereas Cetirizine is given once a day). 2. Pharmacodynamically inappropriate: Dextromethorphan and Cetirizine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. There is no reasonable evidence of efficacy of Phenylephine. 4. There is no rationale in combining four ingredients in single FDC as this will only lead to unnecessary exposure to too many medicines. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 903(E)	Cetirizine + Phenylephrine + Dextromethorphan + Menthol	Meridian Medicare	Cetirizine 5mg+ Phenylephrine 10mg+ Dextromethorphan 10mg+ Menthol 1.5mg syrup	Dry cough & cold	i. Not Submitted ii. Not approved	1.Phamacokinetically incompatible: Dextromethorphan is given 3-4 times a day whereas Cetirizine is given once a day). 2. Pharmacodynamically inappropriate: Dextromethorphan and Cetirizine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. There is no reasonable evidence of efficacy of Phenylephrine. 4. There is no rationale in combining four ingredients in single FDC as this will only lead to unnecessary exposure to too many medicines. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
199	S.O. 903(E)	Cetirizine + Phenylephrine + Dextromethorphan + Menthol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 904(E)	Roxithromycin + Serratiopeptidase	-	-	-	-	1. Pharmacodynamically irrelevant. There is no sound clinical evidence of concurrent use of Roxithromycin & Serratiopeptidase. 2. This combination is not as per standard therapeutic guidelines 3. Serratiopeptidase is not more effective than placebo and has been withdrawn by the innovator. There is no convincing scientific/ clinical evidence/ justification for the FDC.
200	S.O. 904(E)	Roxithromycin + Serratiopeptidase	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 905(E)	Paracetamol + Phenylephrine + Triprolidine	Cipla Ltd.	Paracetamol 325mg+ Phenylephrine HCl 10mg+ Triprolidine 2.5mg uncoated tablet	Common cold associated with fever and body ache.	i. Same as annexure-A ii. Not approved	1. Combining three drugs will lead to unnecessary exposure to three drugs when one may be adequate. All ingredients may not be required at a time. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 905(E)	Paracetamol + Phenylephrine + Triprolidine	Shreya	Each 5 ml contains:Triprolidine Hydrochloride IP 0.625mg + Phenylephrine hydrochloride 5mg+ Paracetamol IP 125mg	Symptomatic relief in common cold/ viral cold, symptoms associated with seasonal allergic rhinitis, symptoms associated with Allergic bronchitis, symptomatic relief in influenza and common flu Symptoms treated effectively were sneezing, rhinorrhoea, itchy nose/palate/throat, itchy/watery/red eyes, fever, cough and expectoration	i. Same as annexure-A ii. Not submitted	1. Combining three drugs will lead to unnecessary exposure to three drugs when one may be adequate. All ingredients may not be required at a time. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 905(E)	Paracetamol + Phenylephrine + Triprolidine	Shreya	Paracetamol 500mg+ Phenylephrine HCl 10mg+ Triprolidine 2.5mg uncoated tablet	Symptomatic relief in common cold/ viral cold, symptoms associated with seasonal allergic rhinitis, symptoms associated with Allergic bronchitis, symptomatic relief in influenza and common flu Symptoms treated effectively were sneezing, rhinorrhoea, itchy nose/palate/throat, itchy/watery/red eyes, fever, cough and expectoration	i. Same as annexure-A ii. Not submitted	1. Combining three drugs will lead to unnecessary exposure to three drugs when one may be adequate. All ingredients may not be required at a time. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
201	S.O. 905(E)	Paracetamol + Phenylephrine + Triprolidine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

379

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 906(E)	Acetaminophen+ Loratadine+ ambroxol + Phenylephrine	Windlas Biotech	Acetaminophen 325mg+ Loratadine 5mg+ Ambroxol HCl 30mg+ Phenylephrine HCl 20mg tablet	It is indicated for relief of irritating and troublesome cough fever and headache	i. Same as annexure-A ii. Not submitted	1. Pharmacokinetically incompatible as loratadine is given once a day and other ingredients are given three to four times a day. 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
202	S.O. 906(E)	Acetaminophen+ Loratadine+ ambroxol + Phenylephrine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

ml

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	I. Indication as per package insert II. Marketing anywhere	
	S.O. 907(E)	Cetirizine + Acetaminophen+ Dextromethorphan + Phenyephrine + Zinc gluconate	-	-	-	-	1. Pharmacokinetically incompatible: Paracetamol and Dextromethorphan are to be given three/four times a day whereas Cetirizine is to be given once a day. 2. Dextromethorphan and Cetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in an FDC. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
203	S.O. 907(E)	Cetirizine + Acetaminophen+ Dextromethorphan + Phenyephrine + Zinc gluconate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

me

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 908(E)	Diphenhydramine + Guaifenesin + Bromhexine + Ammonium Chloride + Menthol	Akums Drugs	Diphenhydramine HCl IP 8mg+ Guaifenesin IP 50mg+ Bromhexine HCL IP 4mg+ Ammonium Chloride IP 100mg+ Menthol IP 1mg per 5ml syrup	Clinical relief of productive cough associated with bronchitis, bronchialasthma, emphysema and other broncho-pulmonary disorders.	i. Same as annexure-A ii. Not approved	1.Pharmacodynamically antagonistic and hence inappropriate (Guaiphenesin, Ammonium chloride, Bromhexine are expectorant/mucolytic whereas Diphenhydramine dries up secretion and is cough supressant). 2. There is no justification for combining three drugs (Guaiphenesin, Ammonium chloride & Bromhexine) with similar effects. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 908(E)	Diphenhydramine + Guaifenesin + Bromhexine + Ammonium Chloride + Menthol	Alembic Ltd.	Diphenhydramine HCl IP 8mg+ Guaifenesin IP 50mg+ Bromhexine HCL IP 4mg+ Ammonium Chloride IP 100mg+ Menthol IP 1mg per 5ml syrup	For Treatment of Productive cough associated with upper and lower respiratory tract disorders	i. Same as annexure-A ii. Not submitted	1.Pharmacodynamically antagonistic and hence inappropriate (Guaiphenesin, Ammonium chloride, Bromhexine are expectorant/mucolytic whereas Diphenhydramine dries up secretion and is cough supressant). 2. There is no justification for combining three drugs (Guaiphenesin, Ammonium chloride & Bromhexine) with similar effects. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 908(E)	Diphenhydramine + Guaifenesin + Bromhexine + Ammonium Chloride + Menthol	Laborate Pharmaceutical	Diphenhydramine HCL IP 8 mg + Guaifenesin IP 50 mg + Bromhexine HCL IP 4 mg + Ammonium Chloride IP 100 mg + Menthol IP 1 mg per 5 ml of Syrup	Cough, Bronchitis, cough relief, Bruising, Chest congestion, Relief of runny nose, Sneezing, itchy, watery eyes, itchy nose, itchy throat due to hay fever or allergy and other conditions.	i. Same as annexure-A ii. Not approved	1.Pharmacodynamically antagonistic and hence inappropriate (Guaiphenesin, Ammonium chloride, Bromhexine are expectorant/mucolytic whereas Diphenhydramine dries up secretion and is cough supressant). 2. There is no justification for combining three drugs (Guaiphenesin, Ammonium chloride & Bromhexine) with similar effects. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 908(E)	Diphenhydramine + Guaifenesin + Bromhexine + Ammonium Chloride + Menthol	Glacier Pharmaceuticals	Diphenhydramine HCl IP 8mg+ Guaifenesin IP 50mg+ Bromhexine HCl IP 4mg + Ammonium Chloride IP 100mg + Menthol IP 1mg per 5ml syrup	antihistaminic, motion sickness antiparkinsonism	i. Not Submitted ii. Not approved	1.Pharmacodynamically antagonistic and hence inappropriate (Guaiphenesin, Ammonium chloride, Bromhexine are expectorant/mucolytic whereas Diphenhydramine dries up secretion and is cough supressant). 2. There is no justification for combining three drugs (Guaiphenesin, Ammonium chloride & Bromhexine) with similar effects. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 908(E)	Diphenhydramine + Guaifenesin + Bromhexine + Ammonium Chloride + Menthol	Varav Biogenesis	Diphenhydramine HCl IP 8mg+ Guaifenesin IP 50mg+ Bromhexine HCL IP 4mg+ Ammonium Chloride IP 100mg+ Menthol IP 1mg per 5ml syrup	Antitussive and expectorant cough mixture	i. Indications mentioned in package insert is different from above. Indications mentioned are: Combination relieves congestion, dries runny nose and postnasal drip and thins mucous to relieve coughing. ii. Not submitted	1.Pharmacodynamically antagonistic and hence inappropriate (Guaiphenesin, Ammonium chloride, Bromhexine are expectorant/mucolytic whereas Diphenhydramine dries up secretion and is cough supressant). 2. There is no justification for combining three drugs (Guaiphenesin, Ammonium chloride & Bromhexine) with similar effects. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
204	S.O. 908(E)	Diphenhydramine + Guaifenesin + Bromhexine + Ammonium Chloride + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Pfizer Ltd.	Chlopheniramine Maleate IP 4mg+ Codeine Phosphate IP 10mg per 5ml syrup	Indicated for dry cough.	Indication mentioned in package insert do not match as above. Indications mentioned in package insert are: Treatment of dry, irritating, disturbing cough in allergic or infective conditions of respiratory passage e.g. Sinusitis, Hay fever, Pharyngitis, Acute Bronchitis, Tuberculosis and tropical eosinophilia. ii. Not Approved	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC. Further, with respect to Annexure A, item 10, information regarding the regulatory status of FDC (Chlorpheniramine + Codeine) was sought from the appellant. In response the appellant has enclosed a 12 page Annexure (Annexure 8). However, the appellant has not stated clearly if the combination of Codeine &Chlorpheniramine is marketed in any of the countries.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Khandelwal Laboratories	Chlopheniramine Maleate IP 4mg+ Codeine Phosphate IP 10mg per 5ml syrup	1. Troublesome bouts of coughing. 2. Dry Unproductive coughs such as those which are associated with Influenza,Whooping cough, Heavy smoking & Allergies. 3. Dry and irritating coughof severe nature which normally occurs due to sinusitis,hay fever,pharyngitis,acute bronchitis,tuberculosis and tropical eosinophilia, etc.	i. Same as annexure-A ii.Approved and marketed in USA, Australia and Singapore.	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Dr. Reddy's Laboratories	Codeine Phosphate IP 10mg+ Chlorpheniramine Maleate IP 4mg per 5ml syrup	For temporary control of cough due to minor throat and bronchial irritation associated with the common cold or inhaled irritants; calms the cough control centre and relieve coughing.	i. Same as annexure-A ii Approved and marketed in USA.	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Laboratories Griffon	Chlopheniramine Maleate IP 4mg+ Codeine Phophate IP 10mg per 5ml syrup	Symptomatic relief of dry cough and related upper respiratory symptoms associated with infection, allergy or the common cold. It is particularly useful for treating dry, painful, unproductive, hacking cough that is unduly exhausting, sleep interfering and hazardous.	Dry irritating non allergic productive cough alone and associated with sneezing, itchy watery eyes, itchy nose or throat and runny nose caused by hay fever(allergic) rhinitis or other respiratory allergies. Smoker's cough.For symptomatic relief in productive cough	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Abbott Healthcare	Codeine Phosphate IP 10mg+ Chlorpheniramine Maleate IP 4mg per 5ml syrup	For Dry Cough.	i. Same as annexure-A ii. Not approved	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Acron Pharmaceuticls	Codeine Phosphate IP 10mg+ Chlorpheniramine Maleate IP 4mg per 5ml syrup	Symptomatic treatment of dry & irritating cough.	i. Same as annexure-A ii. Not approved	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Ozone Pharmaceuticals	Codeine Phosphate IP 10mg+ Chlorpheniramine Maleate IP 4mg per 5ml syrup	It is an effective antiallergic and antitussive, cough syrup for dry cough.	i. Not Submitted ii. Not approved	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Glenmark Pharmaceutical	Codeine Phosphate IP 10mg+ Chlorpheniramine Maleate IP 4mg per 5ml syrup	Temporary relief of cough and upper respiratory tract symptoms including nasal congestion associated with common cold.	i. Indication mentioned in package insert different from above. Indication in package insert is: Relief of cough and symptoms associated with upper respiratory allergies and common cold. ii.Not approved	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Biogenetic Drugs	Chlopheniramine Maleate 10mg+ Codeine Phosphate IP 4mg per 5ml syrup	Broad spectrum antibiotic	i. Not Submitted ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. Indication mentioned by appellant is irrelevant. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Lincoln Parenteral	Chlopheniramine Maleate IP 4mg+ Codeine Phosphate IP 10mg per 5ml syrup	Dry cough and Allergic cough	i. Not Submitted ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Comed Chemicals	Chlopheniramine Maleate 4mg+ Codeine Phosphate IP 10mg per 5ml syrup	In dry cough associated with • Post operative conditions • Allergic Rhinitis • Pharyngitis • Tonsilitis	i. Indication in package insert is different from above. Indication mentioned in package insert is: Relief of cough and symptoms associated with upper respiratory allergies or a common cold. Ii. Not approved	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Anglo-French	Codeine Phophate IP 10mg+ Chlorpheniramine Maleate IP 4mg per 5ml syrup	Dry, URTI associated, irritating allergic cough	i. Not Submitted ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Smilax Healthcare	Chlopheniramine Maleate IP 4mg+ Codeine Phosphate IP 10mg per 5ml syrup	Analgesic, antidiarrheal and cough suppressant	i. Not Submitted ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Skymap Pharmaceutical	Chlopheniramine Maleate 4mg+ Codeine Phosphate IP 10mg per 5ml syrup	Anti cough	i. Not Submitted ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Varav Biogenesis	Chlopheniramine Maleate IP 4mg+ Codeine Phosphate IP 10mg per 5ml syrup	Antihistaminic and cough suppressant	i. Indication mentioned in package insert is different from above. Indication mentioned in package insert is:Sinus sneezing and dry non productive cough. ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Merck Ltd.	Chlopheniramine Maleate IP 4mg + Codeine Phosphate IP 10mg per 5ml syrup	For the relief of dry cough and symptoms associated with upper respiratory allergies or a common cold	i. Indication mentioned in package insert is different from above. Indication mentioned in package insert is:Symptomatic tratment of dry, irritating, disturbing cough in allergic or infective conditions of respiraory passage e.g.: sinusitis, hay fever, pharyngitis, acute bronchitis. ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Somatico Pharmacal Private Ltd.	Chlopheniramine Maleate IP 4mg + Codeine Phosphate IP 10mg per 5ml syrup	Non productive (Dry cough) and Allergic cough	i. Package insert not submitted ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Laborate Pharmaceutical	Chlopheniramine Maleate IP 4mg + Codeine Phosphate IP 10mg per 5ml syrup	Indicated for the relief of cough and symptoms associated with upper respiratory allergies or a coomon cold in adults 18 years of age and older.	i. Indication mentioned in package insert is different from above. Indication mentioned in package insert is: Cough supressant, common cold, Allergy, Hay fever ii. Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Mankind Pharma Ltd	Chlopheniramine Maleate IP 4mg + Codeine Phosphate IP 10mg per 5ml syrup	Indicated for the temprary relief of coughs and upper respiratory symptoms associated with allergy or the common cold.	i. Same as annexure-A ii. Not approved	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	Wings Pharmaceuticals	Chlopheniramine Maleate IP 4mg + Codeine Phosphate IP 10mg per 5ml syrup	Anti-allergic, anti-tussive and for dry cough	i. Indications mentioned in package insert are: Recommended as an anti-tussive for a non productive cough by oral administration. ii. Marketed and approved in India	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further sub-committee noted that: 1.Codeine and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination may cause excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
205	S.O. 909(E)	Chlopheniramine Maleate + Codeine syrup	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 910(E)	Cetirizine + Dextromethorphan + Zinc Gluconate + Menthol	Apex Laboratories	Cetirizine HCl IP 2.5mg+ Dextromethorphan Hbr IP 5mg+ Zinc Gluconate eq. to Elemental Zinc 7.5mg+ Menthol IP 2.5mg per 5ml syrup	Cofstop-z is indicated for the systematic treatment of seasonal allergic rhinitis (hay fever), perennial rhinitis and chronic idiopathic Urticaria, dry, irritating, disturbing cough in allergic or infective conditions of the respiratory passage e.g., sinusitis, pharyngitis, acute bronchitis, tuberculosis, tropical eosinophilia.	i. Same as annexure-A ii. Not submitted	1.Dextromethorphan and Cetirizine both cause sedation and drowsiness and can affect reflexes. It is inappropriate to combine these two drugs in FDC. 2.Pharmacokinetically incompatible: Dextromethorphan has to be given 3-4 times a day whereas Cetirizine is to be given once a day. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 4. Dose of Zinc in this preparation is much less than the minimum dose reported to be clinically beneficial. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
206	S.O. 910(E)	Cetirizine + Dextromethorphan + Zinc Gluconate + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 911(E)	Paracetamol + Phenylephrine + Desloratadine+ Zinc Gluconate + Ambroxol	Varav Biogenesis	Each 5ml contains: Desloratidine 1.25mg + Paracetamol 250mg + Phenylephrine hydrochloride 5mg + Zinc gluconate 10mg + Ambroxol hydrochloride 5mg	Anti-histaminic, Cough and Cold suspension	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Nasal and sinus congestion, cold with cough, allergic symptoms of nose or throat due to upper respiratory tract allergies, sinus pain and headache. ii. Not submitted	1. Pharmacokinetic mismatch: Desloratidine is to be given once a day whereas Paracetamol is given four times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC as this will only lead to unnecessary exposure to too many medicines. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. Dose of Zinc in this preparation is much less than the minimum dose reported to be clinically beneficial. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
207	S.O. 911(E)	Paracetamol + Phenylephrine + Desloratadine+ Zinc Gluconate + Ambroxol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 912(E)	Levocetirizine + Montelukast + Acebrophylline	Macsur	Levocetirizine HCl IP 5mg+ Montelukast sodium IP eq. To Montelukast 10mg+ Acebrophylline 200mg film coated bilayered tablet	For the treatment of Chronic Obstructive pulmonary disease and bronchial asthma with allergic conditions.	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Adjuvant therapy for treatment of bronchial and pulmonary diseases having viscid mucous secretions. Clinical conditions like acute/chronic bronchitis. Chronic Obstructive or Asthma like bronchitis, recurrence of chronic bronchitis and other obstructive diseases. ii. Not Approved	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Acebrophylline, the complex of Ambroxol and Theophylline 1,7 acetate releases very small quantity of Theophylline. Ambroxol (mucolytic) is not recomended in bronchial asthma as per standard treatment guidelines. 3. The treamtent guidelines emphasize inhalation therapy for these diseases and Theophylline has shown modest activity and has been recommended only as a last mode of management. 4. None of the standard treatment guidelines recommend combination of anti-histaminics, leukotriene antagonist and Theophylline or mucolytic. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 912(E)	Levocetirizine + Montelukast + Acebrophylline	Macleods	Levocetirizine HCl IP 5mg+ Montelukast sodium IP 10mg+ Acebrophylline 200mg film coated bilayered tablet	treatment of chronic obstructive pulmonary disease (COPD) and Bronchial asthma (Adults), seasonal and perennial allergic rhinitis, Exercise-Induced Bronchoconstriction (EIB).	i. Package insert does not mention indication of the FDC. ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Acebrophylline, the complex of Ambroxol and Theophylline 1,7 acetate releases very small quantity of Theophylline. Ambroxol (mucolytic) is not recomended in bronchial asthma as per standard treatment guidelines. 3. The treamtent guidelines emphasize inhalation therapy for these diseases and Theophylline has shown modest activity and has been recommended only as a last mode of management. 4. None of the standard treatment guidelines recommend combination of anti-histaminics, leukotriene antagonist and Theophylline or mucolytic. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 912(E)	Levocetirizine + Montelukast + Acebrophylline	Akums Drugs	Montelukast Sodium IP eq. to Montelukast 10mg+ Levocetirizine HCl IP 5mg+ Acebrophylline (SR) 200mg film coated bilayered tablet	Bronchial asthma and COPD.	i. For the treatment of adult patients with Chronic Obstructive Pulmonary Disease (COPD) and Bronchial Asthma and associated rhinitis. ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Acebrophylline, the complex of Ambroxol and Theophylline 1,7 acetate releases very small quantity of Theophylline. Ambroxol (mucolytic) is not recomended in bronchial asthma as per standard treatment guidelines. 3. The treamtent guidelines emphasize inhalation therapy for these diseases and Theophylline has shown modest activity and has been recommended only as a last mode of management. 4. None of the standard treatment guidelines recommend combination of anti-histaminics, leukotriene antagonist and Theophylline or mucolytic. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 912(E)	Levocetirizine + Montelukast + Acebrophylline	Koye Pharmaceuticals	Montelukast Sodium IP eq. to Montelukast 10mg+ Levocetirizine HCl IP 5mg+ Acebrophylline (SR) 200mg film coated bilayered tablet	Bronchial Asthma with co-morbid allergic rhinitis/rhinosinusitis.	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Management of Bronchial Asthma with concomitant Allergic rhinitis/ Sinusitis in adult patients. ii. Not approved	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Acebrophylline, the complex of Ambroxol and Theophylline 1,7 acetate releases very small quantity of Theophylline. Ambroxol (mucolytic) is not recomended in bronchial asthma as per standard treatment guidelines. 3. The treamtent guidelines emphasize inhalation therapy for these diseases and Theophylline has shown modest activity and has been recommended only as a last mode of management. 4. None of the standard treatment guidelines recommend combination of anti-histaminics, leukotriene antagonist and Theophylline or mucolytic. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 912(E)	Levocetirizine + Montelukast + Acebrophylline	Mascot Healthcare	Montelukast Sodium IP eq. to Montelukast 10mg+ Levocetirizine HCl IP 5mg+ Acebrophylline (SR) 200mg film coated tablet	Asthma Prevention	i. Details of individual ingredients submitted but No indication submitted for FDC in package insert ii. Not Submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Acebrophylline, the complex of Ambroxol and Theophylline 1,7 acetate releases very small quantity of Theophylline. Ambroxol (mucolytic) is not recomended in bronchial asthma as per standard treatment guidelines. 3. The treamtent guidelines emphasize inhalation therapy for these diseases and Theophylline has shown modest activity and has been recommended only as a last mode of management. 4. None of the standard treatment guidelines recommend combination of anti-histaminics, leukotriene antagonist and Theophylline or mucolytic. There is no sound scientific/ clinical evidence/ justification for the FDC.
208	S.O. 912(E)	Levocetirizine + Montelukast + Acebrophylline	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 913(E)	Dextromethorphan + Phenylephrine + Ammonium chloride + Menthol	Jenburkt Pharmaceuticals	Dextromethorphan HBr 5mg+ Phenylephrine HCl IP 5mg+ Ammonium Chloride 50mg+ Menthol IP 2.5mg syrup	Cough	i. Not Submitted ii. Not submitted	This FDC was discussed earlier on 23.04.2014 by previous "10 expert Committee" and their comments are as under- "The committee carefully examined the composition of the FDC, it's indication as are available by the manufacturer's submission and also heard the manufacturer's presentations and arguments. In view of the above, the committee observed the following: I. The product combines expectorants and cough suppressants. Thus the product does not target an identifiable patient group. The medical rationale for combining the actives is insufficient." Sub-committee concurs with the opinion of "10 expert committee". The sub-committee noted that: 1. The FDC is Pharmacodynamically inappropriate: Cough suppressants should be avoided in patients with productive cough. So, the combination of expectorants like ammonium chloride with cough suppressants like dextromethorphan is not justified. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
209	S.O. 913(E)	Dextromethorphan + Phenylephrine + Ammonium chloride + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

394

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 914(E)	Dextromethorphan + Bromhexine + Guaiphenesin+ Menthol	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate: Guaiphenesin is an expectorant & Bromhexine is a mucolytic agent; both . It is not appropriate to combine them with Dextromethorphan, which is cough supressant as it hampers expulsion of secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
210	S.O. 914(E)	Dextromethorphan + Bromhexine + Guaiphenesin+ Menthol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 915(E)	Acrivastine+ Paracetamol + Caffeine + Phenylephrine	GKM New Pharma	Acrivastine 8mg+ Paracetamol 325mg+ Caffeine 25mg+ Phenylephrine HCl 5mg tablet	Used in the treatment of Allergic Rhinitis, Hypotensive conditions, Nasal decongestant, eye mydriasis, intraocular tension, seasonal allergic rhinitis	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Allergic rhinitis and Nasal congestion. ii. Not Approved	1. There is no rationale in combining four ingredients in single FDC as this will only lead to unnecessary exposure to too many medicines. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
211	S.O. 915(E)	Acrivastine+ Paracetamol + Caffeine + Phenylephrine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 916(E)	Naphazoline + carboxy Methyl cellulose + Menthol + Camphor + Phenylephrine	Centaur	Naphazoline HCl USP 0.05%w/v +Sodium Carboxymethyl cellulose IP 0.5%w/v+Menthol IP 0.005%w/v+Camphor IP 0.01%w/v+Phenylephrine HCl IP 0.012%w/v eye drops	Ocular congestion and itching associated with dry eyes	i. Ocular congestion, Ocular itching and redness. ii. Not Submitted	1. Pharmacodynamically inappropriate- Multiple ingredients (Menthol & Camphor) with unsubstantiated evidence of safety & benefit in indications claimed by the company. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 916(E)	Naphazoline + carboxy Methyl cellulose + Menthol + Camphor + Phenylephrine	Akums Drugs	Naphazoline HCl USP 0.05%w/v+Sodium Carboxy Methyl cellulose IP 0.50%w/v+Menthol IP 0.005%w/v+Camphor IP 0.01%w/v+Phenylephrine HCl IP 0.012%w/v+Stabilized Oxychloro Complex 0.005%w/v (as preservative) eye drops	Indicated for temporary relief of redness, burning, irritation and discomfort due to dryness of the eye or due to exposure to the wind, dust, sun and computer etc.	i. Indication same as Annexure A. ii.Not Submitted	1. Pharmacodynamically inappropriate- Multiple ingredients (Menthol & Camphor) with unsubstantiated evidence of safety & benefit in indications claimed by the company. There is no sound scientific/ clinical evidence/ justification for the FDC.
212	S.O. 916(E)	Naphazoline + carboxy Methyl cellulose + Menthol + Camphor + Phenylephrine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 917(E)	Dextromethorphan + Cetirizine	Meridian Medicare	Dextromethorphan 10mg+ Cetirizine 5mg tablet	Dry intractable cough	i. Not submitted ii. Not submitted	1. Pharmacodynamically inappropriate: Dextromethorphan and Cetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2. Pharmacokineticincompatibility: Cetirizine is administered once a day whereas Dextromethorphan is administered 3-4 times a day. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
213	S.O. 917(E)	Dextromethorphan + Cetirizine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 918(E)	Nimesulide + Paracetamol + Levocetirizine + Phenylephrine + Caffeine	-	-	-	-	1.Pharmacodynamically inappropriate FDC: Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide, which has adverse effects including hepatotoxicity. Nimesulide formulations for human use in children below 12 years of age is prohibited (GSR NO. 82(E) Dated 10.02.2011) 2. Pharmacokinetic incompatibility: Paracetamol is given 3-4 times a day whereas Levocetirizine is given once a day. 3. Caffeine and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
214	S.O. 918(E)	Nimesulide + Paracetamol + Levocetirizine + Phenylephrine + Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 919(E)	Terbutaline + Ambroxol + Guaiphenesin+ Zinc+ Menthol	-	-	-	-	1. As per the guidelines, mucolytic is not indicated in Asthma. 2. Mucolytic (Ambroxol) alongwith anti-asthmatic drug is liable to be misused as expectorant by patients having cough, exposing them unnecessarily to the anti-asthamatic drug (Terbutaline) and its adverse effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
215	S.O. 919(E)	Terbutaline + Ambroxol + Guaiphenesin+ Zinc+ Menthol	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 920(E)	Codeine + Chlorpheniramine + Alcohol syrup	Abbott Healthcare	Chlorpheniramin maleate IP 4 mg + Codeine Phosphate IP 10 mg + Alcohol IP 0.15 ml	Relief of dry cough	i. Not submitted ii. Not submitted	The Subcommittee noted that the FDC of Chlorpheniramine maleate + Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. The Subcommittee further noted that: 1.Codeine and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as their combination can lead to excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification submitted by the appellant for the FDC.
2M	S.O. 920(E)	Codeine + Chlorpheniramine + Alcohol syrup	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 921(E)	Dextromethorphan + Phenylephrine + Guaifenesin+ Triprolidine	Vivimed Labs	Dextromethorphan HBr IP 10mg+ Phenylephrine HCl IP 5mg + Guaifenesin iP 100mg+ Triprolidine HCl IP 1.25mg per 5ml syrup	For Cough Relief, Nasal Decongestant and Anti-allergic manifestations.	i. Same as per annexure A ii. Not Approved	1. Pharmacodynamically antagonistic and hence inappropriate: Guiaphenesin is an expectorant and it is not appropriate to combine it with Dextromethorphan (a cough suppressant) & Triprolidine (antihistaminic cough suppressant with anti cholinergic properties, which dries up mucous secretions). 2. Dextromethorphan and Triprolidine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3 There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 921(E)	Dextromethorphan + Phenylephrine + Guaifenesin+ Triprolidine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 922(E)	Ammonium Chloride+ Bromhexine + Dextromethorphan	Tirupati Medicare	Ammonium Chloride IP 50mg+ Bromhexine HCl IP 4mg+ Dextromethorphan Hydrobromide IP 5mg per 5ml syrup	Treatment of Cough	Treatment of Cough ii. Not Approved	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients in the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. It is not appropriate to combine them with Dextromethorphan, which is a cough supressant that hampers expulsion of secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per the standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 922(E)	Ammonium Chloride+ Bromhexine + Dextromethorphan	Smilax Healthcare	Ammonium Chloride IP 50mg+ Bromhexine HCl IP 4mg + Dextromethorphan Hbr IP 5mg per 5ml syrup	Anti cough	i. Not submitted ii. Not submitted	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However, the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients in the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. It is not appropriate to combine them with Dextromethorphan, which is a cough supressant that hampers expulsion of secretions. 2. Patient population is not defined. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per the standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 922(E)	Ammonium Chloride+ Bromhexine + Dextromethorphan	Skymap Pharmaceutical	Ammonium Chloride IP 50mg+ Bromhexine HCl IP 4mg+ Dextromethorphan Hydrobromide IP 5mg per 5ml syrup	Anti cough	i. Not submitted ii. Not submitted	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However, the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients in the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. It is not appropriate to combine them with Dextromethorphan, which is a cough supressant that hampers expulsion of secretions. 2. Patient population is not well defined. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per the standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 922(E)	Ammomium Chloride+ Bromhexine + Dextromethorphan	Alkums Drugs & Pharmaceuticals Limited	Each 5ml contains: Dextromethorphan hydrobromide IP 5mg + Bromhexine Hydrochloride IP 3mg + Ammonium chloride IP 50mg	Cough, bronchitis, pulmonary congestion	i. NA ii NA	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However, the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients in the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. It is not appropriate to combine them with Dextromethorphan, which is a cough supressant that hampers expulsion of secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per the standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 922(E)	Ammomium Chloride+ Bromhexine + Dextromethorphan	Skymap Pharmaceutical	Ammomium Chloride IP 50mg+ Bromhexine HCl IP 4mg+ Dextromethorphan Hydrobromide IP 5mg per 5ml mentholated syrup	Expectorant, Cough suppresant	i. Not submitted ii. Not submitted	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However, the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients in the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. It is not appropriate to combine them with Dextromethorphan, which is a cough supressant that hampers expulsion of secretions. 2. Patient population is not well defined. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per the standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
218	S.O. 922(E)	Ammomium Chloride+ Bromhexine + Dextromethorphan	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 923(E)	Diethylcarbamazine + Cetirizine + Ambroxol	-	-	-	-	1. Diethylcarbamazine is indicated in the treatment of filariasis (Tropical pulmonary eosinophillia) while Cetirizine is anti-histaminic drug for treatment of allergic disorders and Ambroxol is a mucolytic agent. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
219	S.O. 923(E)	Diethylcarbamazine + Cetirizine + Ambroxol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 924(E)	Ethylmorphine + Noscapine + Chlorpheniramine Maleate	Valence Healthcare	Ethylmorphine HCl IP 7.5mg+ Noscapine 7.5mg+ Chlorpheniramine Maleate IP 2.5mg oral tablets	Indicated for relief of symptoms associated with colds and influenza such as nasal congestion, sniffing ,headache, minor aches and pains.	i. Not submitted ii. Not submitted	1. Pharmacodynamically inappropriate: Ethylmorphine and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2. Ethylmorphine and Noscapine, both supress cough and dry up secretions. Hence, should not be combined. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
220	S.O. 924(E)	Ethylmorphine + Noscapine + Chlorpheniramine Maleate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 925(E)	Cetirizine + Dextromethorphan + Ambroxol	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate: Ambroxol is a mucolytic agent, which liquifies mucus whereas Dextromethorphan is a cough suppressant, which prevents expulsion of secretions. 2. Dextromethorphan and Cetrizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. Pharmacokinetic incompatibility: Cetirizine is administered once a day whereas Dextromethorphan is administered 3-4 times a day. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
221	S.O. 925(E)	Cetirizine + Dextromethorphan + Ambroxol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 926(E)	Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol	Laborate	Dextromethorphan HBr IP 5mg+ Bromhexine HCl IP 4mg+ Ammonium Chloride IP 50mg+ Menthol IP 2.5mg per 5ml syrup	Cough Suppressant, Expectorant	i. Indications mentioned in package insert are: Relief of persistent dry irritant cough. ii. Not approved	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients of the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. Both increase the respiratory secretions. It is not appropriate to combine them with Dextromethorphan which is a cough supressant and hampers the expulsion of secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 926(E)	Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol	Ind-Swift Ltd.,	Bromhexine HCl IP 8mg+ Dextromethorphan Hbr IP 10mg+ Ammonium Chloride IP 100mg+ Menthol IP 5mg per 10ml syrup	Rising mucous excretion.Affecting the signals in the brain that trigger cough reflex.Increasing the excretion of extracellular electrolytes and water out of the body.Temporary relieving minor pain. During the presentation company representative mentioned that the indication should be recorded as cough supressant and expectorant.	i. Not submitted ii. Not submitted	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients of the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. Both increase the respiratory secretions. It is not appropriate to combine them with Dextromethorphan which is a cough supressant and hampers the expulsion of secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 926(E)	Bromhexine+ Dextromethorphan+ Ammonium Chloride+ Menthol	Akums Drugs	Bromhexine Hydrochloride IP 4mg+ Dextromethorphan Hbr IP 5mg+ Ammonium Chloride IP 50mg+ Menthol IP 2.5mg per 5ml	Treatment of respiratory disorders associated with viscid or excessive mucus or productive cough, which include Tracheobronchitis, Bronchitic with emphysema, Bronchiectasis,Bronchitis with Bronchospasm,Chronic inflammatory pulmonary conditions,Pneumoconiosis.	i. Same as Annexure A ii. Not submitted	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients of the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. Both increase the respiratory secretions. It is not appropriate to combine them with Dextromethorphan which is a cough supressant and hampers the expulsion of secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 926(E)	Bromhexine+ Dextromethorphan+ Ammonium Chloride+ Menthol	DM Pharma	Bromhexine Hydrochloride IP 4mg+ Dextromethorphan Hbr IP 5mg+ Ammonium Chloride IP 50mg+ Menthol IP 2.5mg per 5ml	Cough	i. Cough ii. Not submitted	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients of the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. Both increase the respiratory secretions. It is not appropriate to combine them with Dextromethorphan which is a cough supressant and hampers the expulsion of secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 926(E)	Bromhexine+ Dextromethorphan+ Ammonium Chloride+ Menthol	Skymap Pharmaceuticals Pvt. Ltd.	Bromhexine Hydrochloride IP 4mg+ Dextromethorphan Hbr IP 5mg+ Ammonium Chloride IP 50mg+ Menthol IP 2.5mg per 5ml	Anti-Cough	i. Not Submitted ii. Not submitted	The Subcommittee noted that as per the submission by Sh. Kapil Sibal to the Hon'ble Supreme Court, this FDC is approved before 21.9.1988 (Since February 1983). However the appellant could not produce any documentary evidence. The Subcommittee further noted that: 1. The ingredients of the FDC are pharmacodynamically antagonistic and hence inappropriate: Ammonium Chloride is an expectorant & Bromhexine is a mucolytic. Both increase the respiratory secretions. It is not appropriate to combine them with Dextromethorphan which is a cough supressant and hampers the expulsion of secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
222	S.O. 926(E)	Bromhexine+ Dextromethorphan+ Ammonium Chloride+ Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 927(E)	Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine	Puro Pharma Laboratories	Ambroxol HCl IP 15mg+ Guaiphenesin IP 50mg+ Phenylephrine Hcl IP 5mg+ Chlorpheniramine Maleaet IP 2mg per 5ml syrup	Treatment of Common Cold associated with Throat irritation and Cough.	i. Same as per annexure A ii. Not Approved	1.Pharmacodynamicallyantagonistic and hence inappropriate: Ambroxol and Guaiphenesin are mucolytic/expectorant, and increase respiratory secretions whereas Chlorpheniramine is anti-histaminic cough suppressant (which hampers expulsion of secretions) with anti-cholinergic property that dries up secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification submitted by the appellant for the FDC.
	S.O. 927(E)	Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine	Smilax Healthcare	Ambroxol HCl IP 15mg+ Guaiphenesin IP 50mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine Maleate IP 2mg per 5ml syrup	Mucolytic, Antihistaminic.	i. Not submitted ii. Not submitted	1.Pharmacodynamicallyantagonistic and hence inappropriate: Ambroxol and Guaiphenesin are mucolytic/expectorant, and increase respiratory secretions whereas Chlorpheniramine is anti-histaminic cough suppressant (which hampers expulsion of secretions) with anti-cholinergic property that dries up secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4.This combination is not as per standard therapeutic guidelines. 5. Patient population is not defined. There is no sound scientific/ clinical evidence/ justification submitted by the appellant for the FDC.
	S.O. 927(E)	Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine	Tirupati Medicare	Phenylepherine HCl IP 5mg+ Guaiphenesin IP 50mg+ Chlorpheniramine Maleate IP 2mg + Ambroxol HCL IP 15 mg per 5ml syrup	used to treatment of cough, congestion and cold.	i) Same as Annexure-A ii) Not submitted	1.Pharmacodynamicallyantagonistic and hence inappropriate: Ambroxol and Guaiphenesin are mucolytic/expectorant, and increase respiratory secretions whereas Chlorpheniramine is anti-histaminic cough suppressant (which hampers expulsion of secretions) with anti-cholinergic property that dries up secretions. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification submitted by the appellant for the FDC.
223	S.O. 927(E)	Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

410

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 928(E)	Paracetamol + Phenylephrine + Chlorpheniramine + Zinc Gluconate	-	-	-	-	1. Combining four drugs will lead to unnecessary exposure to these drugs when one may be adequate. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. If the Indication for this FDC is presumed to be common cold then this combination is not as per treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
224	S.O. 928(E)	**Paracetamol + Phenylephrine + Chlorpheniramine + Zinc Gluconate**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 929(E)	Dextromethorphan + Phenylephrine + Cetirizine + Paracetamol + Caffeine	Synchem Laboratories	Dextromethorphan Hbr IP 15mg+ Phenylephrine HCl IP 10mg+ Cetirizine HCl iP 5mg+ Paracetamol IP 500mg+ Caffeine IP 30mg tablet	For symptomatic relief of cough and cold Symptomatic relief of: I. Cough II. Nasal and sinus congestion III. Allergic symptoms of the nose or throat due to upper respiratory tract allergies IV. Sinus pain and headache	i. Not submitted ii. Not submitted	1. Pharmacodynamically inappropriate: Dextromethorphan and Cetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2. Pharmacokinetic incompatibility: Cetirizine is given once a day whereas other ingredients are given three to four times a day. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 929(E)	Dextromethorphan + Phenylephrine + Cetirizine + Paracetamol + Caffeine	Horizon Bioceuticals	Dextromethorphan HBr IP 10mg+ Phenylephrine HCl IP 10mg+ Cetirizine HCl IP 5mg+ Paracetamol IP 500mg+ Caffeine (anhydrous) IP 30mg uncoated tablet	Cough and cold suspension	i. Not submitted ii. Not submitted	1. Pharmacodynamically inappropriate: Dextromethorphan and Cetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2. Pharmacokinetic incompatibility: Cetirizine is given once a day whereas other ingredients are given three to four times a day. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
225	S.O. 929(E)	Dextromethorphan + Phenylephrine + Cetirizine + Paracetamol + Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 930(E)	Dextromethophan + Chlorpheniramine + Guaifenesin + Ammonium Chloride	Laboratories Griffon	Dextromethophan HBr IP 5.0mg+ Chlorpheniramine malcate IP 2.5mg+ Guaifenesin IP 50.0mg + Ammonium Chloride IP 60.0mg per 5ml syrup	For symptomatic treatment ofcough,particularly dry irritating and allergic cough,in conditions like, a. Allergic such as common cold, vasomotor rhinitis. b. Upper respiratory tract infections such as pharyngitis and laryngitis. c. Smoker's cough. d. Acute and chronic bronchitis. e. To supress irritable unproductive cough as in mediastinal compression. f. Whooping cough. g. Bronchiectasis. h. Pulmonary tuberculosis. i. Pneumonia. j. Reflex cough etc.,	i. Indications mentioned in package insert are: For symptomatic treatment of dry, irritating cough and cough of allergic aetiology. ii. Approved in cambodia, Kenya, Mauritius.	The Subcommittee noted that this FDC is approved before 21.9.1988 (Since July 1973) as per the list submitted in the Supreme Court by Sh. Kapil Sibal. However the appellant had no documentary evidence w.r.t the issuance of the license for this FDC prior to 21.9.1988. The appellant did not make technical presentation however the appellant's laywers made legal arguments before the Subcommittee. The appellant's lawyers objected to the hearing given by the Subcommittte to the appellant for this FDC as being outside the jurisdiction of the Subcommitte. The appellant's lawyer read out the Hon'ble Supreme court order as follows: "Insofar as the drugs that have been banned and which were manufactured pre 21st September, 1988, a list of 15 such drugs has been given to us by Mr. Kapil Sibal, learned senior counsel for the respondents. We set aside the Central Government notifications banning them as these cases were never meant to be referred to the Kokate Committee. It will be open, however, for the Central Government, if it so chooses, de novo, to carry out an inquiry as to whether such drugs should be the subject matter of a notification under Section 26A of the Drugs Act." The Subcommittee informed the lawyer of the DTAB Committee's decision in its meeting held on 16.05.2018, the "minutes of the meeting", which are available on CDSCO website are as follows: "The representations of M/s Abbott Health Care Pvt. Ltd. requesting to exclude 15 FDCs approved prior to 1988 and 17 FDCs which were approved by DCG(I) from the list of FDCs in the purview of the Subcommittee constituted for the purpose as per the directions contained in the Honourable Supreme Court judgement were also deliberated by the DTAB. However, the DTAB members deliberated the issues and were of the view that the Subcommittee shall submit the report of all (344 + 05) FDCs again as per the directions from Honourable Supreme Court judgement which also includes the 15 FDCs approved prior to 1988 and 17 FDCs approved by DCG(I). Accordingly, the decision after submission of the report by the Subcommittee would be conveyed to the Ministry of Health and Family Welfare. " Despite the above, the lawyer reiterated the same point. The Subcommittee requested them to submit their representation in writing. No representation was recieved from the firm till 8:00 PM 08.06.2018 date of hearing, representation was received on 19.6.2018.

... contd.

413

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
							As per the public notice, the Subcommittee made its recommendations as per the information already submitted in writing by the appellant. The Subcommittee noted that : 1. The FDC is pharmacodynamically inappropriate: Guiaphenesin & Ammonium Chloride both are expectorants and increase respiratory secretions. It is not appropriate to combine them with Dextromethorphan (a cough supressant) & Chlorpheniramine (an anti-histaminic cough suppressant) which hampers the expulsion of secretions. Moreover, Chlorpheniramine has anti-cholinergic properties that dry up mucous secretions. 2. Chlorpheniramine and Dextromethorphan, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can cause excessive sedation. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 930(E)	Dextromethophan + Chlorpheniramine + Guaifenesin + Ammonium Chloride	Magnet Lab	Dextromethophan HBr IP 10mg+ Chlorpheniramine maleate IP 2.5mg+ Guaifenesin IP 50mg + Ammonium Chloride IP 60.0mg per 5ml syrup	Cough & congestion associated with RTI & allergy for dry cough .	i. Cough & congestion associated with RTI & allergy for dry cough . Ii. Not Submitted	The Subcommittee noted that this FDC is approved before 21.9.1988 (Since July 1973) as per the list submitted in the Supreme Court by Sh. Kapil Sibal. However, the appellant had no documentary evidence The Subcommittee further noted that: 1. The FDC is pharmacodynamically inappropriate: Guiaphenesin & Ammonium Chloride both are expectorants and increase respiratory secretions. It is not appropriate to combine them with Dextromethorphan (a cough supressant) & Chlorpheniramine (an anti-histaminic cough suppressant) which hampers the expulsion of secretions. Moreover, Chlorpheniramine has anti-cholinergic properties that dry up mucous secretions. 2. Chlorpheniramine and Dextromethorphan, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can cause excessive sedation. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 930(E)	Dextromethophan + Chlorpheniramine + Guaifenesin + Ammonium Chloride	Mascot Healthcare	Dextromethophan HBr IP 5mg+ Chlorpheniramine Maleate IP 2.5mg+ Guaiphenesin IP 50mg+ Ammonium Chloride IP 60mg per 5ml syrup	Cough, Rhinitis, Bronchitis	i. Cough, Rhinitis, Bronchitis ii. Not Submitted	The Subcommittee noted that this FDC is approved before 21.9.1988 (Since July 1973) as per the list submitted in the Supreme Court by Sh. Kapil Sibal. However, the appellant had no documentary evidence The Subcommittee further noted that: 1. The FDC is pharmacodynamically inappropriate: Guiaphenesin & Ammonium Chloride both are expectorants and increase respiratory secretions. It is not appropriate to combine them with Dextromethorphan (a cough supressant) & Chlorpheniramine (an anti-histaminic cough suppressant) which hampers the expulsion of secretions. Moreover, Chlorpheniramine has anti-cholinergic properties that dry up mucous secretions. 2. Chlorpheniramine and Dextromethorphan, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can cause excessive sedation. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 930(E)	Dextromethophan + Chlorpheniramine + Guaifenesin + Ammonium Chloride	Biogenetic Drugs	Dextromethophan Hbr IP 5mg+ Chlorpheniramine Maleate IP 2.5mg+ Guaiphenesin 50mg+ Ammonium Chloride 60mg per 5mlsyrup	Broad spectrum antibiotic.	i. Not submitted ii. Not submitted	The Subcommittee noted that this FDC is approved before 21.9.1988 (Since July 1973) as per the list submitted in the Supreme Court by Sh. Kapil Sibal. However, the appellant had no documentary evidence The Subcommittee further noted that: 1. The indication for the FDC provided by the appellant is irrelevant and wrong in view of the ingredients and cannot be therapeutically justified. 2. The FDC is pharmacodynamically inappropriate: Guiaphenesin & Ammonium Chloride both are expectorants and increase respiratory secretions. It is not appropriate to combine them with Dextromethorphan (a cough supressant) & Chlorpheniramine (an anti-histaminic cough suppressant) which hampers the expulsion of secretions. Moreover, Chlorpheniramine has anti-cholinergic properties that dry up mucous secretions. 3. Chlorpheniramine and Dextromethorphan, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can cause excessive sedation. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert II. Marketing anywhere	
	S.O. 930(E)	Dextromethophan + Chlorpheniramine + Guaifenesin + Ammonium Chloride	Sirmour Remedies	Dextromethophan HBr IP 10mg+ Chlorpheniramine maleate IP 2.5mg+ Guaifenesin IP 50.0mg + Ammonium Chloride IP 60.0mg per 5ml syrup	Cough & Congestion associated with RTI & allergy for dry cough	i. Cough & Congestion associated with RTI & allergy for dry cough II. Not submitted	The Subcommittee noted that this FDC is approved before 21.9.1988 (Since July 1973) as per the list submitted in the Supreme Court by Sh. Kapil Sibal. However the appellant had no documentary evidence. The Subcommittee further noted that: 1. The FDC is pharmacodynamically inappropriate: Guiaphenesin & Ammonium Chloride both are expectorants and increase respiratory secretions. It is not appropriate to combine them with Dextromethorphan (a cough supressant) & Chlorpheniramine (an anti-histaminic cough suppressant) which hampers the expulsion of secretions. Moreover, Chlorpheniramine has anti-cholinergic properties that dry up mucous secretions. 2. Chlorpheniramine and Dextromethorphan, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can cause excessive sedation. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 930(E)	Dextromethophan + Chlorpheniramine + Guaifenesin + Ammonium Chloride	DM Pharma	Dextromethophan HBr IP 10mg+ Chlorpheniramine maleate IP 2.5mg+ Guaifenesin IP 50.0mg + Ammonium Chloride IP 60.0mg per 5ml syrup	Allergic cold, Cough and cold	i. Allergic rhinitis, common cold and cough ii. Not submitted	The Subcommittee noted that this FDC is approved before 21.9.1988 (Since July 1973) as per the list submitted in the Supreme Court by Sh. Kapil Sibal. However, the appellant had no documentary evidence The Subcommittee further noted that: 1. The FDC is pharmacodynamically inappropriate: Guiaphenesin & Ammonium Chloride both are expectorants and increase respiratory secretions. It is not appropriate to combine them with Dextromethorphan (a cough supressant) & Chlorpheniramine (an anti-histaminic cough suppressant) which hampers the expulsion of secretions. Moreover, Chlorpheniramine has anti-cholinergic properties that dry up mucous secretions. 2. Chlorpheniramine and Dextromethorphan, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can cause excessive sedation. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
226	S.O. 930(E)	Dextromethophan + Chlorpheniramine + Guaifenesin + Ammonium Chloride	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 931(E)	Levocetirizine + Dextromethorphan + Zinc	Creative Healthcare	Levocetirizine HCl IP 0.8mg+ Dextromethorphan HBr IP 10mg+ Zinc elemental 7.5mg (as Zinc Gluconate) per 5ml syrup	Cough Syrup	i. Not submitted ii. As per firm, this FDC is marketed in India.	1. Pharmacodynamically inappropriate: Dextromethorphan and Levocetrizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2.Pharmacokinetic incompatibility: Levocetirizine is administered once a day while Dextromethorphan is administered 3-4 times a day. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification submitted by the appellant for the FDC.
227	S.O. 931(E)	Levocetirizine + Dextromethorphan + Zinc	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 932(E)	Paracetamol + Phenylephrine + Levocetirizine + Caffeine	Alembic Ltd.	Paracetamol IP 500mg+ Phenylephrine HCl IP 10mg+ Caffeine (Anhydous) IP 30mg+ Levocetirizine HCl IP 2.5mg tablet	symptomatic relief of common cold when this condition is associated with nasal congestion, headache, mild pain, rhinorrhoea and sneezing.	i. Indications mentioned in package insert are: Rhinosinusitis, Cold, Flu. Ii. Not Approveed	1. Pharmacokinetic incompatibility: Levocetirizine is administered once a day whereas Paracetamol is administered 3-4 times a day. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 932(E)	Paracetamol + Phenylephrine + Levocetirizine + Caffeine	Geno Pharmaceuticals	Paracetamol IP 325mg+ Phenylephrine HCl IP 10mg+ Caffeine (Anhydous) IP 15mg+ Levocetirizine HCl IP 2.5mg film coated tablet	Symptomatic relief of common cold with pain, fever, nasal congestion in adults.	i. Not submitted ii. Not submitted	1. Pharmacokinetic incompatibility: Levocetirizine is administered once a day whereas Paracetamol is administered 3-4 times a day. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 932(E)	Paracetamol + Phenylephrine + Levocetirizine + Caffeine	Alembic Ltd.	Paracetamol IP 500mg+ Phenylephrine HCl IP 10mg+ Caffeine (Anhydous) IP eq. to Caffeine 30mg+ Levocetirizine HCl IP 2.5mg uncoated tablet	symptomatic relief of common cold when this condition is associated with nasal congestion, headache, mild pain, rhinorrhoea and sneezing.	i. Indications mentioned in package insert are: Rhinosinusitis, Cold, Flu. Ii. Not Approveed	1. Pharmacokinetic incompatibility: Levocetirizine is administered once a day whereas Paracetamol is administered 3-4 times a day. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 932(E)	Paracetamol + Phenylephrine + Levocetirizine + Caffeine	Puro Pharma Laboratories	Levocetirizine HCl IP 2.5mg+ Phenylephrine Hcl IP 10mg+ Paracetamol IP 500mg+ Caffeine anhydrous IP eq. to Caffeine 30mg tablet	Common cold and Allergic Rhinitis.	i. Common cold and Allergic Rhinitis. Ii. Not Submitted	1. Pharmacokinetic incompatibility: Levocetirizine is administered once a day whereas Paracetamol is administered 3-4 times a day. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 932(E)	Paracetamol + Phenylephrine + Levocetirizine + Caffeine	Mascot Healthcare	Levocetirizine HCl IP 2.5mg+ Phenylephrine Hcl IP 2.5mg+ Paracetamol IP 325mg+ Caffeine anhydrous IP eq. to Caffeine 25mg uncoated tablet	Nasal congestion associated with cold	i. Not submitted ii. Not submitted	1. Pharmacokinetic incompatibility: Levocetirizine is administered once a day whereas Paracetamol is administered 3-4 times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 932(E)	Paracetamol + Phenylephrine + Levocetirizine + Caffeine	Meridian Medicare	Paracetamol IP 325mg+ Phenylephrine HCl IP 10mg+ Caffeine (Anhydous) IP 30mg+ Levocetirizine HCl IP 5mg tablet	Anti allergic, anticold	i. Not submitted ii. Not submitted	1. Pharmacokinetic incompatibility: Levocetirizine is administered once a day whereas Paracetamol is administered 3-4 times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 932(E)	Paracetamol + Phenylephrine + Levocetirizine + Caffeine	Meridian Medicare	Paracetamol IP 325mg+ Phenylephrine HCl IP 10mg+ Caffeine (Anhydous) IP 30mg+ Levocetirizine HCl IP 5mg tablet	Anti allergic, anticold	i) Not submitted ii) Not submitted	1. Pharmacokinetic incompatibility: Levocetirizine is administered once a day whereas Paracetamol is administered 3-4 times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
228	S.O. 932(E)	**Paracetamol + Phenylephrine + Levocetirizine + Caffeine**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 933(E)	Chlorpheniramine + Ammonium Chloride + Sodium Chloride	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate: Chlorpheniramine is an anti histaminic cough suppressant having anti cholinergic properties which decreases mucous secretion while Ammonium Chloride and Sodium chloride increase the mucus secretion in respiratory tract. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
229	S.O. 933(E)	Chlorpheniramine + Ammonium Chloride + Sodium Chloride	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 934(E)	Paracetamol + Dextromethorphan + Bromhexine + Phenylephrine + Diphenhydramine	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate: Bromhexine is mucolytic and liquifies mucus whereas Dextromethorphan (a cough suppressant) and Diphenhydramine (an anti-histaminic cough suppressant) hamper the expulsion of mucus secretion. Diphenhydraminealso has anti-cholinergic properties which decrease mucous secretion. 2. Dextromethorphan and Diphenhydramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
230	S.O. 934(E)	**Paracetamol + Dextromethorphan + Bromhexine + Phenylephrine + Diphenhydramine**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 935(E)	Salbutamol + Bromhexine + Guaiphenesin + Menthol	Indoco Remedies	Bromhexine HCl IP 2mg+ Salbutamol Sulphate IP eq. To Salbutamol 1mg+ Guaiphenesin IP 50mg+ Menthol IP 0.5mg per 5ml syrup	For symptomatic management of productive cough associated with respiratory conditions like bronchitis, pneumonia, acute exacerbations of chronic bronchitis, bronchiecstasis.	i. Same as per annexure A ii. Not Approved	1. Mucolytic (Bromhexine) and expectorant (Guaiphenesin) alongwith anti-asthmatic drug is liable to be misused as expectorant by patients having productive cough, exposing them unnecessarily to the anti-asthamatic drug (Salbutamol) and its adverse effects. 2. Salbutamol is preferred as an inhalation rather than oral. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 935(E)	Salbutamol + Bromhexine + Guaiphenesin + Menthol	Laborate Pharmaceutical	Salbutamol Sulphate IP eq. to Salbutamol 2mg+ Bromhexine HCl IP 4mg+ Guaiphenesin IP 50mg+ Menthol IP 0.5mg per 10ml syrup	Bronchodilator, Expectorant, Mucolytic.	i. Same as per annexure A ii. Not Approved	1. . Patient population is not well defined. 2. Mucolytic (Bromhexine) and expectorant (Guaiphenesin) alongwith anti-asthmatic drug is liable to be misused as expectorant by patients having productive cough, exposing them unnecessarily to the anti-asthamatic drug (Salbutamol) and its adverse effects. 3. Salbutamol is preferred as an inhalation rather than oral. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
231	S.O. 935(E)	Salbutamol + Bromhexine + Guaiphenesin + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 936(E)	Chlorpheniramine + Ammonium Chloride + Noscapine + Sodium Citrate	Biological E	Chlorpheniramine maleate IP 4mg+ Ammonium Chloride IP 28mg + Noscapine IP 15mg+ Sodium Citrate IP 6.5ml per 5ml syrup	For control of dry non-productive cough or if cough is unduly tiring and disturbs sleep.	i) For suppression of continuous and irritating cough and for facilitation of expectoration ii) Coscopin linctusApproved in Nigeria, Yemen, malawai	1. Pharmacodynamically inappropriate: Noscapine is cough supressant, Chlorpheniramine is an anti Histaminic, cough supressant and anti cholinergic which dries up secretion whereas Ammonium chloride and Sodium citrate are expectorants. 2. Chlorpheniramine reduces sensitivity of cough centre & causes drowsiness while expectorants increase secretions. This may lead to aspiration in children. Therefore, the combination is irrational with potential of causing adverse effects. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 936(E)	Chlorpheniramine + Ammonium Chloride + Noscapine + Sodium Citrate	Biological E	Chlorpheniramine maleate IP 2mg+ Ammonium Chloride IP 28mg + Noscapine IP 7mg+ Sodium Citrate IP 3.25ml per 5ml syrup	For control of dry non-protective cough or if cough is unduly tiring and disturbs sleep.	i) For suppression of continuous and irritating cough and facilitation of expectoration.ii) Not approved	1. Pharmacodynamically inappropriate: Noscapine is cough supressant, Chlorpheniramine is an anti Histaminic, cough supressant and anti cholinergic which dries up secretion whereas Ammonium chloride and Sodium citrate are expectorants. 2. Chlorpheniramine reduces sensitivity of cough centre & causes drowsiness while expectorants increase secretions. This may lead to aspiration in children. Therefore, the combination is irrational with potential of causing adverse effects. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
232	S.O. 936(E)	Chlorpheniramine + Ammonium Chloride + Noscapine + Sodium Citrate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 937(E)	Cetirizine + Dextromethorphan + Bromhexine + Guaifenesin	-	-	-	-	1. Pharmacodynamically inappropriate: Dextromethorphan and Cetrizine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. Dextromethorphan is cough supressant whereas Bromhexine is mucolytic and Guaiphenesin is expectorant. 2.Pharmacokinetic mismatch: Cetirizine is administered once a day while Dextromethorphan is administered 3-4 times a day. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
233	S.O. 937(E)	Cetirizine + Dextromethorphan + Bromhexine + Guaifenesin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 938(E)	Diethyl Carbamazine + Chlorpheniramine + Guaifenesin	Common Health Pharmaceuticals	Diethyl Carbamazine Citrate 50mg+ Guaiphenesin 50mg+ Chlorpheniramine Maleate 1mg per 5ml liquids	Tropical pulmonary eosinophilia	i) Not submitted ii) Not approved	1. Pharmacodynamically inappropriate:For the management of Tropical Pulmonary Eosinophilia (TPE), patient needs only one ingredient (Diethyl Carbamazine). 2. Guaiphenesin and Chlorpheniramine are not indicated for management of TPE. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 938(E)	Diethyl Carbamazine + Chlorpheniramine + Guaifenesin	Common Health Pharmaceuticals	Diethyl Carbamazine Citrate 100mg+ Guaiphenesin 60mg+ Chlorpheniramine Maleate 2mg tablet	Tropical pulmonary eosinophilia	i) Not submitted ii) Not approved	1. Pharmacodynamically inappropriate:For the management of Tropical Pulmonary Eosinophilia (TPE), patient needs only one ingredient (Diethyl Carbamazine). 2. Guaiphenesin and Chlorpheniramine are not indicated for management of TPE. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 938(E)	Diethyl Carbamazine + Chlorpheniramine + Guaifenesin	Uni-San Pharmaceuticals	Diethyl Carbamazine Citrate 100mg+ Guaiphenesin 60mg+ Chlorpheniramine Maleate 2mg uncoated tablet	for tropical pulmonary & Eosinophilia (For free breathing & for reduced wheezing)	i) Not submitted ii) Not submitted	1. Pharmacodynamically inappropriate:For the management of Tropical Pulmonary Eosinophilia (TPE), patient needs only one ingredient (Diethyl Carbamazine). 2. Guaiphenesin and Chlorpheniramine are not indicated for management of TPE. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
234	S.O. 938(E)	Diethyl Carbamazine + Chlorpheniramine + Guaifenesin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 939(E)	Ketotifen + Cetirizine	-	-	-	-	1.Pharmacokinetic mismatch: Ketotifen is given twice a day whereas Cetirizine is given once a day. 2. There is no evidence of any benefit from combining two anti-histamines. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
235	S.O. 939(E)	Ketotifen + Cetirizine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 940(E)	Terbutaline + Bromhexine + Etofylline	Chinubhai Pharma	Terbutaline sulphate IP eq. to Terbutaline 5mg+ Bromhexine HCl IP 8mg+ Etofylline IP 200mg uncoated tablet	For the relief of bronchospasm in adults and children 6 years of age and older with reversible obstructive airway disease due to asthma, chronic bronchitis or COPD.	i)For the relief of bronchospasm in adults and children 8 years of age and older with reversible obstructive airway disease due to asthma, chronic bronchitis or COPD. ii) Not submitted	1. The recommended standard therapy of bronchial asthma and COPD is by inhalation route. 2. This combination is not as per standard therapeutic guidelines. 3. Use of mucolytic alongwith anti-asthmatic drug is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drug (Terbutaline, Etophylline) and its adverse effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
236	S.O. 940(E)	**Terbutaline + Bromhexine + Etofylline**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 941(E)	Ketotifen + Theophylline	Lark Laboratories	Ketotifen Fumarate eq. to Ketotifen 1mg+ Theophylline (anhydrous) 200mg tablet	Prophylaxis of asthma.	i) Not submitted ii) Not submitted	1. Theophylline has narrow margin of safety and is not suitable for FDC as per guidelines. 2. Theophylline has no role in prevention of asthma. 3. Pharmacokinetic mismatch: Ketotifen is given twice a day whereas Theophylline is given thrice a day. 4. This combination is not recommended in standard treatment guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
237	**S.O. 941(E)**	**Ketotifen + Theophylline**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 942(E)	Ambroxol + Salbutamol + Theophylline	-	-	-	-	1. Theophylline has a narrow therapeutic index and is not suitable in FDC as per guidelines. 2. Currently, the recommended standard therapy of bronchial asthma and COPD is by inhalation route. 3. Mucolytics are not recommended in asthma. 4. Use of mucolytic alongwith anti-asthmatic drug is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drug (Salbutamom & Theophylline) and its adverse effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
238	S.O. 942(E)	Ambroxol + Salbutamol + Theophylline	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 943(E)	Cetirizine + Nimesulide + Phenylephrine	-	-	-	-	1.Nimesulide has adverse effects including hepatotoxicity. Nimesulide formulations for human use in children below 12 years of age is prohibited (GSR NO. 82(E) Dated 10.02.2011) 2.Pharmacokinetic mismatch: Nimesulide is given two times a day whereas Cetirizine is given once a day and phenylephrine four times a daily. 3. There is no resonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
239	S.O. 943(E)	Cetirizine + Nimesulide + Phenylephrine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 944(E)	Chlorpheniramine + Phenylephrine+ Paracetamol+ Zinc Gluconate	-	-	-	-	1. Combining four drugs will lead to unnecessary exposure to these drugs when one may be adequate. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. This combination is not as per standard therapeutic guidelines. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. There is no sound scientific/ clinical evidence/ justification for the FDC.
240	S.O. 944(E)	Chlorpheniramine + Phenylephrine+ Paracetamol+ Zinc Gluconate	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

ane

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 945(E)	Acetaminophen+ Guaifenesin+ Dextromethorphan+ Chlorpheniramine	-	-	-	-	1.Pharmacodynamically inappropriate as Dextromethorphan is Anti tussive (cough supressant), Chlorpheniramine is Anti Histaminic, anti-tussive and anti cholinergic which dries up mucous secretion while Guaiphenesin is expectorant have opposing actions and not suitable as FDC. 2. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. There is no rationale in combining four ingredients in single FDC as this will only lead to unnecessary exposure to too many medicines. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
241	S.O. 945(E)	Acetaminophen+ Guaifenesin+ Dextromethorphan+ Chlorpheniramine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 946(E)	Cetirizine + Dextromethorphan + Phenylephrine + Tulsi	Varav Biogenesis	Cetirizine HCl IP 5mg+ Phenylephrine HCl IP 5mg+ Dextromethorphan HBr IP 5mg+ Tulasi (as extract) IP 0.1%v/v per 5ml syrup	Cough and Cold suppression.	i)Relief of nasal and sinus congestion, cough associated with allergy, relief of allergic symptoms of the nose throat due to upper respiratory tract allergies, Adjunct with antibacterial in sinusitis tonsillitis and otitis media. ii) Not submitted	1.Pharmacokinetically incompatible: Dextromethorphan is given three to four times a day whereas Cetirizine is given once a day. 2. Dextromethorphan and Cetrizine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
242	**S.O. 946(E)**	**Cetirizine + Dextromethorphan + Phenylephrine + Tulsi**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 947(E)	Cetirizine + Phenylephrine + Paracetamol+ Ambroxol + Caffeine	-	-	-	-	1.Pharmacokinetic mismatch: Paracetamol is given 3-4 times a day and Cetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
243	S.O. 947(E)	Cetirizine + Phenylephrine + Paracetamol+ Ambroxol + Caffeine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 948(E)	Guaifenesin+ Dextromethorphan	-	-	-	-	1.Pharmacodynamically inappropriate as Dextromethorphan is cough supressant while Guaiphenesin is expectorant, both have opposing actions and not suitable as FDC. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
244	S.O. 948(E)	Guaifenesin+ Dextromethorphan	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 949(E)	Levocetirizine + Paracetamol + Phenylephirine + Caffeine	Akums Drugs	Levocetirizine HCl IP 5mg/2.5mg/2.5mg+ Paracetamol IP 500mg/325mg/500mg+ Phenylephirine HCl IP 5mg/10mg/10mg + Caffeine (Anhydrous) 30mg/30mg/15mg uncoated tablet	Rhinosinusitis, colds, flu	i)The combination is indicated and provides complete relief from symptoms of common cold and nasal decongestion and associated fever due to allergic reactions.The combination has synergistic mucolytic,antihistaminic and nasal decongestant actions.This relieves multiple symptoms of congestion,blocked,runny nose,itching and sneezing and at the same time loosens viscid mucus as well as cough associated with nasal congestion as in respiratory tract infections/allergies. ii) Not approved	1. There is pharmacokinetic incompatibility: Paracetamol is given three to four times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 949(E)	Levocetirizine + Paracetamol + Phenylephirine + Caffeine	Akums Drugs	Levocetirizine HCl IP 2.5mg+ Paracetamol IP 500mg+ Phenylephirine HCl IP 10mg+ Caffeine (Anhydrous) 15mg uncoated tablet	To treat rhinosinusitis, colds, flu	i)The combination is indicated and provides complete relief from symptoms of common cold and nasal decongestion and associated fever due to allergic reactions.The combination has synergistic mucolytic,antihistaminic and nasal decongestant actions.This relieves multiple symptoms of congestion,blocked,runny nose,itching and sneezing and at the same time loosens viscid mucus as well as cough associated with nasal congestion as in respiratory tract infections/allergies. ii) Not approved	1. There is pharmacokinetic incompatibility: Paracetamol is given three to four times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 949(E)	Levocetirizine + Paracetamol + Phenylephirine + Caffeine	Unison	Levocetirizine HCl IP 2.5mg+ Paracetamol IP 500mg+ Phenylephirine HCl IP 10mg + Caffeine (Anhydrous) 30mg uncoated tablet	For rhinosinusitis, colds, flu.	i) Same ii) Not approved	1. There is pharmacokinetic incompatibility: Paracetamol is given three to four times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 949(E)	Levocetirizine + Paracetamol + Phenylephirine + Caffeine	Centaur	Levocetirizine HCl IP 2.5mg+ Paracetamol IP 500mg+ Phenylephirine HCl IP 10mg + Caffeine (Anhydrous) 30mg tablet	Common cold and allergic rhinitis.	i) Not submitted ii)Not submitted	1. There is pharmacokinetic incompatibility: Paracetamol is given three to four times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
245	S.O. 949(E)	Levocetirizine + Paracetamol + Phenylephirine + Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Centaur	Phenylephrine HCl IP 10mg+ Chlorpheniramine maleate IP 2mg+ Paracetamol IP 500mg+ Caffeine IP (anhydrous) 30mg tablet	Common cold	i) Same ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Lifestar	Phenylephrine HCl IP 10mg+ Chlorpheniramine maleate IP 2mg+ Paracetamol IP 500mg+ Caffeine IP (anhydrous) 30mg uncoated tablet	Use in the treatment of symptoms associated with common cold and allergic rhinitis (i: e Fever, Sneezing, nasal decongestion, headache, running nose)	i)Use in the treatment of symptoms associated with common cold , flu and allergic rhinitis ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Juggat	Phenylephrine HCl IP 5mg+ Chlorpheniramine maleate IP 2mg+ Paracetamol IP 500mg+ Caffeine IP (anhydrous) 15mg uncoated tablet	Indicated in cold associated with fever.	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Geno	Phenylephrine HCl IP 5mg+ Chlorpheniramine maleate IP 2mg+ Paracetamol IP 325mg+ Caffeine IP (anhydrous) 30mg uncoated tablet	Symptomatic relieve of common cold with pain, fever, nasal congestion in adults.	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Akums Drugs	Caffeine Anhydrous IP 15mg/20mg/30mg/16mg/30mg/15mg + Paracetamol IP 500mg/500mg/325mg/325mg/325mg/325mg+ Phenylephrine HCl IP 5mg/5mg/5mg/10mg/10mg/10mg + Chlorpheniramine Maleate IP 2mg/2mg/2mg/4mg/2mg/4mg tablet	Nasal Congestion, Common cold, Rhinorrhoea, fever with common cold, allergic cough	i) Same as Annexure-A. ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Cipla Ltd.	Caffeine 25mg+ Paracetamol 325mg+ Phenylephrine 5mg+ Chlorpheniramine 2mg uncoated tablet	Temporarily relieves these symptoms of hay fever or other upper respiratory allergies: • Headache, Sinus congestion and pressure, nasal congestion, runny nose and sneezing, minor aches and pains Temporarily relieves these additional symptoms of hay fever • Itching of the nose or throat, Itchy, watery eyes, Helps clear nasal passages. Helps decongest sinus openings and passages.	i) Same as Annexure-A. ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Alembic Ltd.	Caffeine IP 16mg+ Paracetamol IP 500mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine maleate IP 2mg uncoated tablet	symptomatic relief ofcommon cold when this condition is associated with nasal decongestion,headache,mild pain,rhinorrhea and sneezing	i) Same as Annexure-A. ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Unison Pharmaceuticals	Caffeine Anhydrous IP 15mg/30mg+ Paracetamol IP 500mg/500mg+ Phenylephrine HCl IP 5mg/10mg+ Chlorpheniramine maleate IP 2mg/4mg uncoated tablet	Symptomatic treatment of colds, acute viral infections of the respiratory tract including influenza (Fever, pain and Rhinorrhoea.)	i) Same as Annexure-A. ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Creative Healthcare	Caffeine anhydrous IP 30mg+ Paracetamol IP 500mg+ Phenylephrine HCl IP 10mg+ Chlorpheniramine maleate IP 2mg uncoated tablet	Not submitted	i. Not submitted ii. As per firm, this FDC is maarketed in India.	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Mepromax Lifesciences	Caffeine (Anhydrous) 30mg+ Paracetamol 500mg+ Phenylephrine HCl 5mg+ Chlorpheniramine Maleate 2mg tablets	Not mentioned	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	SKN Organics	Caffeine (Anhydrous) 15mg+ Paracetamol 250mg+ Phenylephrine HCl 5mg+ Chlorpheniramine Maleate 1mg uncoated tablets	Fever Pain, Pain associated with migraine headache. Pain associated with Osteoarthritis. Headache relieves fatigue. Relieve discomfort in common cold. Relieve allergic symptoms.	i) Relief of nasal and sinus congestion, relief of allergic symptoms of nose or throat due to upper respiratory tract allergies, relief of sinus pain and headache, adjunct with anti bacterial in sinusitis, tonsillitis and otitis media. ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	HAB Pharmaceuticals	Caffeine (Anhydrous) 30mg+ Paracetamol IP 325mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablets	Analgesic and Anti-inflammatory agents. Helps in achieving long-lasting relief from cold and flu symptoms. It is effective for Fever including cold and flu allergic rhinitis, blocked nose, sinusitis headache, sore throat, chesty cough and for relieving associated aches and pains	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Skan Research	Caffeine (Anhydrous) 30mg+ Paracetamol 650mg+ Phenylephrine HCl 10mg+ Chlorpheniramine Maleate 2mg uncoated tablets	Fever ,pain,pain associated with migraine headache,pain associated with osteoarthritis,headache,relieve fatigue,relieves discomfort in common cold	i) Relief of nasal and sinus congestion, relief of allergic symptoms of nose or throat due to upper respiratory tract allergies, relief of sinus pain and headache, adjunct with anti bacterial in sinusitis, tonsillitis and otitis media. ii) Not approved	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Mepromax Lifesciences	Caffeine IP (Anhydrous) 30mg+ Paracetamol IP 500mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablets	Not mentioned	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Skymap Pharmaceutical	Caffeine (Anhydrous) 25mg+ Paracetamol 325mg+ Phenylephrine HCl 5mg+ Chlorpheniramine Maleate 2mg uncoated tablets	Is used as anti cough	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Skymap Pharmaceutical	Caffeine (Anhydrous) 30mg+ Paracetamol 325mg+ Phenylephrine HCl 5mg+ Chlorpheniramine Maleate 2mg uncoated tablets	Is used as anti cough	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Shiva Biogenetic	Caffeine (Anhydrous) 30mg+ Paracetamol 325mg+ Phenylephrine HCl 5mg+ Chlorpheniramine Maleate 2mg uncoated tablets	Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Horizon Bioceuticals	Caffeine Anhydrous IP 30mg+ Paracetamol IP 500mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine maleate IP 2mg uncoated tablet	Multi symptom cold relief such as flu, fever, congestion, stuffy nose and decongestant(antipyretic, analgesic and decongestant)	i) Same as Annexure- A. ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Lark Laboratories	Caffeine (Anhydrous) IP 20mg+ Paracetamol IP 325mg+ Phenylephrine HCL IP 10mg+ Chlorpheniramine Maleate IP 4mg uncoated tablet	Is used for symptomatic relief of common cold and flu.	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Aishwarya Celebrity	paracetamol IP 325mg+ phenylephrine hydrocholride IP 5mg+ chlorpheniramine Maleate IP 2mg + caffeine (anhydrous) IP 50mg uncoated tablet	Is used as anti cold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	DM Pharma	Phenylephrine HCl IP 5mg+ Paracetamol IP 325mg+ Caffeine IP 30mg+ Chlorpheniramine maleate IP 2mg uncoated tablet	Is used for allergic rhinitis, hay fever, fever associated with cough and cold.	i) Same as Annexure- A. ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Meridian Medicare	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 325mg+ Phenylephrine HCL IP 5mg+ Chlorpheniramine Maleate IP 4mg tablet	Is used as anti cold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 16mg+ Paracetamol IP 300mg+ Phenylephrine HCL IP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Antipyretic and Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 325mg+ Phenylephrine HCL IP 10mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Antipyretic and Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 20mg+ Acetaminophen IP 350mg+ Phenylephrine HCL IP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Antipyretic and Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 20mg+ Paracetamol IP 325mg+ Phenylephrine HCL IP 5mg+ Chlorpheniramine Maleate IP 4mg uncoated tablet	Antipyretic and Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) BP 30mg+ Paracetamol BP 325mg+ Phenylephrine HCL BP 5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Antipyretic and Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 325mg+ Phenylephrine HCL BP 10mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Antipyretic and Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 500mg+ Phenylephrine HCL BP 10mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 500mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 500mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 300mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 500mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 4mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 15mg+ Paracetamol IP 300mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 20mg+ Paracetamol IP 300mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 4mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 15mg+ Paracetamol IP 300mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 15mg+ Paracetamol IP 300mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 300mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 500mg+ Phenylephrine HCL BP 10mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 20mg+ Paracetamol IP 500mg+ Phenylephrine HCL BP 5mg+ Chlorpheniramine Maleate IP 4mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 20mg+ Paracetamol IP 300mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 4mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 15mg+ Paracetamol IP 300mg+ Phenylephrine HCL BP 2.5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 500mg+ Phenylephrine HCL BP 5mg+ Chlorpheniramine Maleate IP 2mg per 3 gm sachet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 30mg+ Paracetamol IP 500mg+ Phenylephrine HCL BP 5mg+ Chlorpheniramine Maleate IP 2mg per 5gm sachet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Combitic Global	Caffeine (Anhydrous) IP 20mg+ Paracetamol IP 500mg+ Phenylephrine HCL BP 5mg+ Chlorpheniramine Maleate IP 4mg uncoated tablet	Anti-pyretic &Anticold	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Comed Chemicals Ltd.	Phenylephrine HCl 10mg + Chlorpheniramine maleate 2mg + Paracetamol 325mg + Caffeine 30mg tablet	Nasal congestion and common cold associated with fever and Headache	i. Indication same as Annexure A. ii Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	Comed Chemicals Ltd.	Phenylephrine HCl 10mg + Chlorpheniramine maleate 2mg + Paracetamol 500mg + Caffeine 30mg tablet	Nasal congestion and common cold associated with fever and Headache	i. Indication same as Annexure A. ii Not submitted	The Subcommittee noted that this FDC is approved prior to 1988. Comments of the Subcommittee are as under: 1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
246	S.O. 950(E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 951(E)	Ketotifen + Levocetrizine	-	-	-	-	1.Pharmacokinetic mismatch: Ketotifen is given twice a day whereas Levocetirizine is given once a day. 2. There is no evidence of any benefit from combining two anti-histamines. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
247	S.O. 951(E)	Ketotifen + Levocetrizine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 952(E)	Paracetamol + Levocetirizine + Phenylephirine + Zinc Gluconate	PharmaSynth	Paracetamol IP 325mg+ Levocetirizine HCl IP 2mg+ Phenylephirine HCl IP 10mg+ Zinc Gluconate USP eq. to elemental Zinc 7.5mg tablet	Antihistamine and Antipyretics.	i. Not submitted ii. Not submitted	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Dose of Zinc in this preparation is much less than the minimum dose reported to be clinically beneficial. 5. Patient population is not properly defined. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
248	S.O. 952(E)	Paracetamol + Levocetirizine + Phenylephirine + Zinc Gluconate	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 953(E)	Paracetamol + Phenylephrine + Triprolidine + Caffeine	PharmaSynth	Paracetamol IP 325mg+ Phenylephrine HCL IP 5mg+ Triprolidine HCl IP 1.25mg+ Caffeine (Anhydrous) IP 15mg uncoated tablet	Antihistaminic and antipyretic	i. Not submitted ii. Not submitted	1. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
249	S.O. 953(E)	Paracetamol + Phenylephrine + Triprolidine + Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 954(E)	Caffeine + Paracetamol + Phenylephrine + Cetirizine	Akums Drugs	Caffeine 30mg/30mg/30mg+ Paracetamol IP 500mg/500mg/325mg+ Phenylephrine HCl IP 10mg/10mg/10mg+ Cetirizine HCl 2.5mg/5mg/5mg film coated tablet	Indicated for rhinosinusitis, colds, flu	i. Same as annexure A ii. Not submitted	1. Pharmacokinetic mismatch: Cetirizine is administered once a day whereas Paracetamol is administered three to four times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 954(E)	Caffeine + Paracetamol + Phenylephrine + Cetirizine	J.B. Chemicals	Caffeine IP 30mg+ Paracetamol IP 325mg+ Phenylephrine HCl IP 10mg+ Cetirizine HCl IP 5mg uncoated tablet	Fixed dose combination (FDC) of CetrizineHCl, Paracetamol, Phenylepherine& Caffeine is indicated for the symptomatic treatment of common cold, allergic rhinitis, fever and nasal congestion.	i. Same as annexure A ii. Not submitted	1. Pharmacokinetic mismatch: Cetirizine is administered once a day whereas Paracetamol is administered three to four times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 954(E)	Caffeine + Paracetamol + Phenylephrine + Cetirizine	Mascot Healthcare	Caffeine IP 25mg+ Paracetamol IP 325mg+ Phenylephrine HCl IP 10mg+ Cetirizine HCl IP 5mg uncoated tablet	analgesia,respiratory depression,nasal congestion,cold,pain and fever	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: The firm has mentioned indications of individual ingredients and not for the FDC. ii.Not submitted	1. Pharmacokinetic mismatch: Cetirizine is administered once a day whereas Paracetamol is administered three to four times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 954(E)	Caffeine + Paracetamol + Phenylephrine + Cetirizine	Anglo-French	Caffeine (anhydrous) IP 30mg+ Paracetamol IP 325mg+ Phenylephrine HCl IP 10mg + Cetirizine HCl IP 5mg uncoated tablet	common cold and flu	i. Not submitted ii. Not submitted	1. Pharmacokinetic mismatch: Cetirizine is administered once a day whereas Paracetamol is administered three to four times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 954(E)	Caffeine + Paracetamol + Phenylephrine + Cetirizine	Synchem	Caffeine IP 30mg+ Paracetamol IP 500 mg+ Phenylephrine HCl IP 10mg + Cetirizine diHCl IP 5mg tablet	Symptomatic relief in cold and cough.Symptomatic relief of: i. Nasal and Sinus congestion ii. Allergic symptoms of the nose or throat due to upper respiratory tract allergies iii. Sinus pain and headache	i. Same as annexure A ii. Not Approved	1. Pharmacokinetic mismatch: Cetirizine is administered once a day whereas Paracetamol is administered three to four times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 954(E)	Caffeine + Paracetamol + Phenylephrine + Cetirizine	Wings Pharmaceuticals Pvt. Ltd.	Caffeine IP 30mg+ Paracetamol IP 325 mg+ Phenylephrine HCl IP 10mg + Cetirizine HCl IP 5mg tablet	Blocked nose, Headache, Bodyache, Backache, Sneezing, runny nose and Sore throat	i. Same as annexure A ii. Not Approved	1. Pharmacokinetic mismatch: Cetirizine is administered once a day whereas Paracetamol is administered three to four times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
250	S.O. 954(E)	Caffeine + Paracetamol + Phenylephrine + Cetirizine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 955(E)	Dextromethorphan + Phenylephirine + Guaifenesin	-	-	-	-	1.Pharmacodynamically inappropriate: Dextromethorphan is cough supressant while Guaiphenesin is an expectorant. Both have opposing actions and are not suitable as FDC. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
251	S.O. 955(E)	Dextromethorphan + Phenylephirine + Guaifenesin	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 956(E)	Ambroxol + Levocetirizine + Phenylephrine + Guaiphenesin + Menthol	Mascot Healthcare	Ambroxol HCl IP 15mg + Levocetirizine Di-HCl IP 0.8mg + Phenylephrine HCl IP 5mg + Guaiphenesin IP 50mg+ Menthol IP 2.5mg per 5ml syrup	Cough and cold	i. Same as annexure A ii. Not Approved	1. Pharmacokinetically incompatible: Ambroxol is given three times a day whereas Levocetrizine is given once a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 956(E)	Ambroxol + Levocetirizine + Phenylephrine + Guaiphenesin + Menthol	DM Pharma	Ambroxol HCL IP 15mg+ Levocetirizine HCL IP 0.8mg+ Phenylephrine HCl IP 5mg+ Guaiphenesin IP 50mg+ Menthol per 5ml syrup	Is used in the treatment of cough associated with nasal congestion as a respiratory tract infection/allergy	i. Indication not mentioned in package insert. ii. Not submitted	1. Pharmacokinetically incompatible: Ambroxol is given three times a day whereas Levocetrizine is given once a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
252	S.O. 956(E)	Ambroxol + Levocetirizine + Phenylephrine + Guaiphenesin + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 957(E)	Pseudoephedrine + Cetirizine	Combitic Global	Pseudoephedrine HCl IP 60mg+ Cetirizine Dihydrochloride IP 10mg uncoated tablet	Is used in the treatment of Anti allergic	i. Not submitted ii. Not submitted	DTAB Subcommittee noted that FDC of Cetirizine Dihydrochloride 5mg (Immediate release) + Pseudoephedrine HCl 120mg (SR) tablet for the treatment of seasonal allergic rhinitis was approved by CDSCO on 09.09.1997. However, the Subcommittee noted that there is: 1. Pharmacokinetic mismatch as cetirizine is given once a day whereas Pseudoephedrine is given three times a day. 2. Patient population for which this FDC is indicated is not well defined. 3. The indication mentioned by the company is "As an anti allergic agent". Pseudoephedrine is not required for the claimed indication. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
253	S.O. 957(E)	Pseudoephedrine + Cetirizine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 958(E)	Dextromethorphan + Chlorpheniramine + Ammonium Chloride + Menthol	-	-	-	-	1.Pharmacodynamically inappropriate: Dextromethorphan is cough supressant and Chlorpheniramine is anti histaminic, cough supressant and anti cholinergic which dries up mucous secretion whereas Ammonium Chloride is expectorant. 2. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. This combination is not as per standard therapeutic guidelines. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
254	S.O. 958(E)	Dextromethorphan + Chlorpheniramine + Ammonium Chloride + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 959(E)	Paracetamol + Caffeine + Phenylephrine + Chlorpheniramine	Glenmark	Paracetamol IP 325mg + Caffeine (Anhydrous) IP 30mg+ Phenylephrine HCl IP 10mg+ Chlorpheniramine Maleate IP 2mg tablet	For the symptomatic treatment of cough, nasal congestion, runny nose and discomfort with rhinosinusitis, cold & flu.	i. Same as annexure A ii. Not Approved	1. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 959(E)	Paracetamol + Caffeine + Phenylephrine + Chlorpheniramine	Micro	Paracetamol IP 325mg + Caffeine (Anhydrous) IP 30mg+ Phenylephrine HCl IP 10mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	For management for symptoms of common cold.	i. Same as annexure A ii. Not Approved	1. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 959(E)	Paracetamol + Caffeine + Phenylephrine + Chlorpheniramine	Ind-Swift Ltd.,	Paracetamol IP 500mg+ Caffeine (Anhydrous) IP 30mg+ Phenylephrine HCL IP 5mg+ Chlorpheniramine Maleate IP 2mg uncoated tablets	Relief of nasal and sinus congestion, Relief of allergic symptoms of the nose or throat due to upper respiratory tract allergies, Relief of sinus pain and headache, Adjunct with anti bacterials in sinusitis, tonsillitis and otitis media.	i. Not submitted ii. Not submitted	1. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 959(E)	Paracetamol + Caffeine + Phenylephrine + Chlorpheniramine	Mascot Healthcare	Paracetamol IP 325mg+ Caffeine IP 30mg+ Phenylephrine HCl IP 10mg + Chlorpheniramine Maleate IP 2mg uncoated tablet	relieve fever ,pain,	i. Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Indications of individual ingredients have been mentioned instead of FDC. ii. Not approved	1. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
255	S.O. 959(E)	Paracetamol + Caffeine + Phenylephrine + Chlorpheniramine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 960(E)	Salbutamol + Aminophylline + Guaifenesin	-	-	-	-	1. Aminophylline has a narrow therapeutic index. Hence, not suitable in FDC as per guidelines. 2. The recommended standard therapy of bronchial asthma and COPD is by inhalation route. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
258	S.O. 960(E)	Salbutamol + Aminophylline + Guaifenesin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 961(E)	Salbutamol + Theophylline + Bromhexine	Spectrum Pharmaceuticals	Pellets of Salbutamol HCl IP 8mg+ Pellets of Thoephylline eq. to Thoephylline (anhydrous) IP 200mg+ Pellets of Bromhexine HCl IP 8mg capsules	Asthma and COPD	i. Same as annexure A ii. Not Approved	1. Theophylline has a narrow therapeutic index and is not suitable in FDC as per guidelines. 2. The recommended standard therapy of bronchial asthma and COPD is by inhalation route. 3. Mucolytic agent (Bromhexine) is not recommended in bronchial asthma as per guidelines. 4. Use of mucolytic alongwith anti-asthmatic drugs is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drugs (Salbutamol & Theophylline) and their adverse effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
257	S.O. 961(E)	Salbutamol + Theophylline + Bromhexine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 962(E)	Chlorpheniramine + Dextromethorphan + Guaifenesin + Phenylephrine	Juggat Pharma	Chlorpheniramine Maleate IP 4mg+ Dextromethorphan Hbr IP 10mg+ Guaiphenesin IP 100mg+ Phenylephrine HCl IP 5mg per 5ml syrup	Indicated in cough and cold	i. Not submitted ii. Not submitted	1. Pharmacodynamically inappropriate: Chlorpheniramine, an anti histaminic with anti cholinergic properties dries up secretions and hampers the action of expectorant (Guaiphenesin). Dextromethorphan is cough supressant whereas Guaiphenesin is expectorant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 962(E)	Chlorpheniramine + Dextromethorphan + Guaifenesin + Phenylephrine	Glenmark Pharmaceutical	Chlorpheniramine Maleate 4 mg + Dextromethorphan HCL 10 mg + Guaiphenesin 100 mg + Phenylephrine HCL 5 mg per 5 ml Syrup	Temporary relief of cough due to minor throat and bronchial irritation as may occur with a cold or allergy.	i. Same as annexure A ii. Not Approved	1. Pharmacodynamically inappropriate: Chlorpheniramine, an anti histaminic with anti cholinergic properties dries up secretions and hampers the action of expectorant (Guaiphenesin). Dextromethorphan is cough supressant whereas Guaiphenesin is expectorant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 962(E)	Chlorpheniramine + Dextromethorphan + Guaifenesin + Phenylephrine	Glenmark Pharmaceutical	Chlorpheniramine Maleate 4 mg + Dextromethorphan HCL 10 mg + Guaiphenesin 100 mg + Phenylephrine HCL 5 mg per 5 ml Syrup (Sorbitol Sugar Free base)	Temporary relief of cough due to minor throat and bronchial irritation as may occur with a cold or allergy.	i. Same as annexure A ii. Not Approved	1. Pharmacodynamically inappropriate: Chlorpheniramine, an anti histaminic with anti cholinergic properties dries up secretions and hampers the action of expectorant (Guaiphenesin). Dextromethorphan is cough supressant whereas Guaiphenesin is expectorant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 962(E)	Chlorpheniramine + Dextromethorphan + Guaifenesin + Phenylephrine	Franklin Laboratories	Dextromethorphan HBr IP 10mg+ Guaiphenesin IP 100mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine Maleate IP 4mg per 5ml syrup	Not mentioned.	i. Not submitted ii. Not submitted	1. Pharmacodynamically inappropriate: Chlorpheniramine, an anti histaminic with anti cholinergic properties dries up secretions and hampers the action of expectorant (Guaiphenesin). Dextromethorphan is cough supressant whereas Guaiphenesin is expectorant. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. There is no sound scientific/ clinical evidence/ justification for the FDC.
258	S.O. 962(E)	**Chlorpheniramine + Dextromethorphan + Guaifenesin + Phenylephrine**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

464

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	Franklin Laboratories	Caffeine Anhdrous IP 30mg+ Paracetamol IP 325mg+ Chlorpheniramine Maleate IP 4mg uncoated tablet	Not mentioned.	i. Not submitted ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	Combitic Global	Caffeine IP 15mg+ Paracetamol IP 325mg+ Chlorpheniramine maleate IP 4mg uncoated tablet	Anti-pyretic & Anticold	i. Not submitted ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	Combitic Global	Caffeine IP 20mg+ Paracetamol IP 325mg+ Chlorpheniramine maleate IP 4mg uncoated tablet	Anti-pyretic &Anticold	i. Not submitted ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	Combitic Global	Caffeine IP 20mg+ Paracetamol IP 325mg+ Chlorpheniramine maleate IP 4mg uncoated tablet	Anti-pyretic &Anticold	i. Not submitted ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	Combitic Global	Caffeine IP 30mg+ Paracetamol IP 500mg+ Chlorpheniramine maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i. Not submitted ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	Combitic Global	Caffeine IP 20mg+ Paracetamol IP 300mg+ Chlorpheniramine maleate IP 4mg uncoated tablet	Anti-pyretic &Anticold	i. Not submitted ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	Combitic Global	Caffeine IP 30mg+ Paracetamol IP 500mg+ Chlorpheniramine maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i. Not submitted ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	Combitic Global	Caffeine IP 30mg+ Paracetamol IP 500mg+ Chlorpheniramine maleate IP 2mg uncoated tablet	Anti-pyretic &Anticold	i. Not submitted ii. Not submitted	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	Wings Pharmaceuticals Pvt. Ltd.	Caffeine IP 30mg+ Paracetamol IP 325mg+ Chlorpheniramine maleate IP 4mg uncoated tablet	Antihistaminic, Analgesic and Antipyretic	i. Same as annexure A ii. Not Approved	1. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
259	S.O. 963(E)	Caffeine + Paracetamol+ Chlorpheniramine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 964(E)	Ammonium Chloride+ Dextromethophan+ Cetirizine + Menthol	Mascot Healthcare	Ammonium Chloride IP 50mg+ Dextromethophan Hbr IP 5mg+ Cetirizine HCl IP 2.5mg+ Menthol IP 2.5mg per 5ml syrup	An inhalant to relieve nasal,bronchial or upper respiratory congestion,sneezing and cold	i. Same as annexure A ii. Not Approved	1. Pharmacodynamically inappropriate: Ammonium chloride is an expectorant whereas Dextromethorphan is a cough supressant. 2. Dextromethorphan and cetirizine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. Pharmacokinetic mismatch: Cetirizine is administered once a day whereas Dextromethorphan is administered three to four times a day. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 964(E)	Ammonium Chloride+ Dextromethophan+ Cetirizine + Menthol	Wings Pharmaceuticals Pvt. Ltd.	Ammonium Chloride IP 100mg+ Dextromethophan Hbr IP 10mg+ Cetirizine HCl IP 5mg+ Menthol IP 5mg per 5ml syrup	For productive cough and cold	i. Same as annexure A ii. Not Approved	1. Pharmacodynamically inappropriate: Ammonium chloride is an expectorant whereas Dextromethorphan is a cough supressant. 2. Dextromethorphan and cetirizine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. Pharmacokinetic mismatch: Cetirizine is administered once a day whereas Dextromethorphan is administered three to four times a day. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
260	S.O. 964(E)	Ammonium Chloride+ Dextromethophan+ Cetirizine + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 965(E)	Dextromethorphan + Paracetamol+ Cetirizine + Phenylephrine	PharmaSynth	Dextromethorphan HBr IP 5 mg + Paracetomol IP 125 mg + Phenylephrine HCL IP 5 mg + Cetrizine Hydrochloride IP 2 mg per 5 ml Syrup	Antihistamine and Antipyretic	i) Not submitted ii) Not submitted	1. Pharmacodynamically inappropriate: Cetirizine and Dextromethorphan both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2. There is a Pharmacokinetic mismatch. Paracetamol & Dextromethorphan are given four times a day whereas Cetirizine is given once a day 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
261	S.O. 965(E)	Dextromethorphan + Paracetamol+ Cetirizine + Phenylephrine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 966(E)	Chlorpheniramine + Terpin + Antimony Potassium Tartrate+ Ammoniumchloride+ SodiumCitrate+ Menthol	-	-	-	-	1. Pharmacodynamically inappropriate: Chlorpheniramine is an anti histaminic, cough supressant and anti cholinergic which dries up mucous secretion whereas Ammonium chloride and Sodium citrate are expectorants. 2. There is no rationale in combining six ingredients in single FDC. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. 4. Terpine is an obsolete expectorant which has been withdrawn in USA due to lack of efficacy. There is no sound scientific/ clinical evidence/ justification for the FDC.
262	S.O. 966(E)	Chlorpheniramine + Terpin + Antimony Potassium Tartrate+ Ammoniumchloride+ SodiumCitrate+ Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 967(E)	Terbutaline Sulphate+ Etofylline+ Ambroxol	Chinubhai Pharma	Terbutaline IP 2.5mg+ Etofylline IP 100mg+ Ambroxol IP 30mg tablet	Asthma, chronic bronchitis, chronic obstructive pulmonary disease emphysema mucous bronchiectasis.	i) Indication same as Annexure-A ii) Not Approved	1. There is no therapeutic justification for the ingredients to be combined for the stated indications. 2. This combination is not as per standard therapeutic guidelines. 3. Indication mentioned by the company also does not specify the definitive patient population (e.g. not responding to the first line treatment) that may benefit. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 967(E)	Terbutaline Sulphate+ Etofylline+ Ambroxol	Seagull	Terbutaline IP 2.5mg+ Etofylline IP 100mg+ Ambroxol IP 30mg tablet	For the treatment of acute respiratory tract disease with impaired formulation of secretions. Treatment of respiratory disorder	I) Not submitted ii) Not submitted	1. There is no therapeutic justification for the ingredients to be combined for the stated indications. 2. This combination is not as per standard therapeutic guidelines. 3. Indication mentioned by the company also does not specify the definitive patient population (e.g. not responding to the first line treatment) that may benefit. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
263	S.O. 967(E)	Terbutaline Sulphate+ Etofylline+ Ambroxol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 968(E)	Paracetamol+ Codeine+ Chlorpheniramine	Anglo-French	Paracetamol IP 325mg+ Codeine Phophate IP 10mg+ Chlorpheniramine Maleate IP 2mg uncoated tablet	Common cold and flu.	i) To control the constellation of symptoms associated with common cold & Flu ii) Not Approved	1. Codeine and Chlorpheniramine both cause sedation and drowsiness and that may lead to excessive sedation. It is inappropriate to combine these two drugs in FDC. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. The risk benefit ratio is unfavourable and the FDC is irrational. There is no sound scientific/ clinical evidence/ justification for the FDC.
264	S.O. 968(E)	Paracetamol+ Codeine+ Chlorpheniramine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC.** **The FDC may involve risk to human beings.** **Hence in the larger public interest it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 969(E)	Paracetamol + Pseudoephedrine + Cetirizine + Caffeine	-	-	-	-	1. There is pharmacokinetic incompatibility: Paracetamol is given three to four times a day whereas Levocetirizine is given once a day. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects.. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
265	S.O. 969(E)	Paracetamol + Pseudoephedrine + Cetirizine + Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 970(E)	Chlorpheniramine + Ammonium Chloride + Menthol	-	-	-	-	1. Pharmacodynamically inappropriate: Chlorpheniramine is an anti-histaminic, cough supressant and anti cholinergic which dries up mucous secretion whereas ammonium chloride is expectorant. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
266	S.O. 970(E)	Chlorpheniramine + Ammonium Chloride + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 971(E)	N-Acetyl Cysteine + Ambroxol + Phenylephrine + Levocetirizine	-	-	-	-	1. Pharmacokinetically inappropriate: Levocetirizine is given once a day whereas Amborxol & Phenylephrine is given three times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
267	S.O. 971(E)	N-Acetyl Cysteine + Ambroxol + Phenylephrine + Levocetirizine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 972(E)	Dextromethorphan + Phenylephrine + Triprolidine + Menthol	-	-	-	-	1. Pharmacodynamically inappropriate: Dextromethorphan and Triprolidine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
268	S.O. 972(E)	Dextromethorphan + Phenylephrine + Triprolidine + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 973(E)	Salbutamol + Cetirizine + Ambroxol	-	-	-	-	1. Pharmacokinetically incompatible: Salbutamol is given three-four times a day whereas Cetirizine is given once a day. 2. The recommended standard therapy of bronchial asthma and COPD is by inhalation route. 3. Mucolytics are not indicated in treatment of Asthma as per guidelines.. 4. Use of mucolytic alongwith anti-asthmatic drug is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drug (salbutamol) and its adverse effects. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
269	S.O. 973(E)	Salbutamol + Cetirizine + Ambroxol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 974(E)	Dextromethorphan + Phenylephrine + Bromhexine + Guaifenesin+ Chlorpheniramine	-	-	-	-	1.Pharmacodynamically inappropriate: Dextromethorphan & Chlorpheniramine are cough suppressants & Chlorpheniramine dries up secretions whereas Bromhexine & Guaiphenesin are mucolytic/expectorants. 2. There is no rationale in combining five ingredients in single FDC.Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 4. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 5. This combination is not as per standard therapeutic guidelines. 6. Moreover, Fixed dose combination of centrally acting, antitussive with antihistamine, having high atropine like activity in expectorants is banned. (As per GSR NO. 395(E) Dated 19.05.1999) There is no sound scientific/ clinical evidence/ justification for the FDC.
270	S.O. 974(E)	Dextromethorphan + Phenylephrine + Bromhexine + Guaifenesin+ Chlorpheniramine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 975(E)	Nimesulide+ Cetirizine+ Phenylephrine	-	-	-	-	1. Pharmacokinetically incompatible: Nimesulide is given twice a day whereas Cetirizine is given once a day and Phenylephrine is administered four times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. This combination is not as per standard therapeutic guidelines. 4. Use of Nimesulide is banned below the age of 12 years due to potential hepatotoxicity. There is no sound scientific/ clinical evidence/ justification for the FDC.
271	S.O. 975(E)	Nimesulide+ Cetirizine+ Phenylephrine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 976(E)	Naphazoline +Chlorpheniramine + Zinc Sulphate +Boric Acid Ip+ Sodium chloride + chlorobutol	NuLife	Naphazoline HCl USP 0.056%w/v +Chlorpheniramine Maleate IP 0.01%w/v+Zinc Sulphate IP 0.12%w/v+Boric Acid IP 1.25%w/v+Sodium chloride IP 0.05%w/v+chlorobutol IP 0.35%w/v eye drops	Redness and minor irritations of the eye caused by the dusty atmosphere wind swimming smoke air pollutants and close work etc.	i. Indication same as Annexure A. ii.Not Submitted	The Subcommittee noted that this FDC has SLA approval prior to 1988. The company provided information regarding safety and efficacy of individual ingredients. However, no published study is available with this FDC/ combination of these drugs. Further, Subcommittee noted that: 1. FDC is Pharmacodynamically inappropriate- Multiple ingredients with unsubstantiated evidence of benefit in indications claimed by the company for this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
972	S.O. 976(E)	Naphazoline + Chlorpheniramine + Zinc Sulphate + Boric Acid Ip+ Sodium chloride + chlorobutol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 977(E)	Paracetamol+ Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin	Akums Drugs	Paracetamol IP 325mg+ Bromhexine HCl IP 8mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine Maleate IP 2mg+ Guaifenesin IP 100mg film coated table	Nasal congestion	i) Cold, Chills, influenza and chesty cough. ii) Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1.There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Bromhexine is a mucolytic agent and both increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously for the conditions stated and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 977(E)	Paracetamol+ Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin	Cipla Ltd.	Paracetamol 325mg+ Bromhexine HCL 8mg + Phenylephrine hCl 10mg + Chlorpheniramine maleate 2mg+ Guaifenesin 100mg tablet	Acute rhinitis sinusitis cough and cold associated with headache body ache and fever (Flu like symptoms)	i) Same as Annexure A ii) Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1.There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Bromhexine is a mucolytic agent and both increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously for the conditions stated and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 977(E)	Paracetamol+ Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin	Mascot Healthcare	Paracetamol IP 325mg+ Bromhexine HCl IP 8mg+ Phenylephrine HCl IP 10mg + Chlorpheniramine Maleate IP 2mg+ Guaiphenesin IP 100mg uncoated tablet	Cough, cold, fever and bodyache	i) Not Mentioned (Individual components indications mentioned) ii) NA	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1.There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Bromhexine is a mucolytic agent and both increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously for the conditions stated and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 977(E)	Paracetamol+ Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin	Laborate Pharma	Paracetamol IP 325 mg + Bromhexine HCL IP 4 mg + Phenylephrine HCL IP 5 mg + Chlorpheniramine Maleate IP 4 mg + Guaifenesin IP 50 mg uncoated tablets	Anti-cough, anti-cold, anti-allergic, anti-pyretic, Analgesic	i) Synergistically to relieve cough. Also antipyretic,painkiller,anti-allergic effects ii) Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1.There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Bromhexine is a mucolytic agent and both increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously for the conditions stated and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 977(E)	Paracetamol+ Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin	Skymap Pharmaceutical	Paracetamol IP 325mg+ Bromhexine HCl IP 8mg+ Phenylephrine HCl IP 5mg + Chlorpheniramine Maleate IP 2mg+ Guaiphenesin IP 100mg uncoated tablet	Anti cough	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1.There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Bromhexine is a mucolytic agent and both increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously for the conditions stated and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 977(E)	Paracetamol+ Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin	Skymap Pharmaceutical	Paracetamol IP 325mg+ Bromhexine HCl IP 8mg+ Phenylephrine HCl IP 5mg + Chlorpheniramine Maleate IP 2mg+ Guaiphenesin IP 100mg uncoated tablet	Anti cough	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1.There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Bromhexine is a mucolytic agent and both increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously for the conditions stated and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 977(E)	Paracetamol+ Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin	Group Pharmaceuticals	Paracetamol + Bromhexine+ Phenylephrine HCl+ Chlorpheniramine Maleate + Guaiphenesin tablet	Not submitted	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1.There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Bromhexine is a mucolytic agent and both increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously for the conditions stated and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 977(E)	Paracetamol+ Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin	Horizon Bioceuticals Pvt. Ltd.	Paracetamol IP 450mg + Guaiphenesin 50mg + Chlorpheniramine maleate 4mg + Phenylephrine 5mg + Bromhexine HCl 4mg uncoated tablets	Cough & Cold	i. Indication mentioned in package insert are different from Annexure A. Indicaions mentioned in pack insert are: Cold associated with cough, Relief of allergic symptoms of the nose or throat due to upper respiratory tract allergies, Relief of sinus pain and headache, adjunct with antibacterials in sinusitis, tonsilitis and otitis media. ii. NA	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee further noted that: 1.There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Bromhexine is a mucolytic agent and both increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC. Patients may not need all the ingredients simultaneously for the conditions stated and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
273	S.O. 977(E)	Paracetamol+ Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 978(E)	Salbutamol+ Bromhexine	-	-	-	-	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the Subcommmittee could not find any documentary evidence in this regard. The Subcommittee further noted that: 1. Inhaled Salbutamol is more efficacious and safer than oral Salbutamol in the management of bronchial asthma. 2. Mucolytic (Bromhexine) is not indicated in bronchial asthma as per guidelines. 3. Mucolytic (Bromhexine) alongwith anti-asthmatic drug is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drug (Salbutamol) and its adverse effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
274	S.O. 978(E)	Salbutamol+ Bromhexine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 979(E)	Dextromethorphan + Phenylephrine + Guaifenesin + Cetirizine + Acetaminophen	Horizon Bioceuticals	Dextromethorphan Hbr IP 10 mg + Phenylephrine HCL IP 10 mg + Guaifenesin IP 50 mg + Cetirizine HCL IP 5 mg + Acetaminophen IP 500 mg uncoated tablets	Cough & Cold	i) Cold associated with cough • Relief of allergic symptoms of the nose or throat due to upper respiratory tractallergies. • Relief of sinus pain and headache. ii) Not Submitted	1.Pharmacodynamically inappropriate {Cough suppressant (Dextromethorphan) and expectorant (Guaiphenesin) are combined} 2. Dosing schedule is incompatible. (Acetaminophen is given 3-4 times a day whereas Cetirizine is given once a day). 3. Dextromethorphan and Cetirizine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 4. There is no rationale in combining five ingredients in single FDC as this will only lead to unnecessary exposure to too many medicines. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. There is no sound scientific/ clinical evidence/ justification for the FDC.
275	S.O. 979(E)	**Dextromethorphan + Phenylephrine + Guaifenesin + Cetirizine + Acetaminophen**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 980(E)	Guaifenesin+ Bromhexine+ Chlorpheniramine+ Paracetamol	NA	NA	NA	NA	1. Pharmacodynamically antagonistic and hence inappropriate: Guaiphenesin and Bromhexine are expectorant/mucolytic which increase mucus secretion & should not be given in combination with Chlorpheniramine (an antihistaminic cough suppressant with anti-cholinergic properties) which supresses cough and dries up secretions . 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
276	S.O. 980(E)	Guaifenesin+ Bromhexine+ Chlorpheniramine+ Paracetamol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 981(E)	Chlorpheniramine+ Ammonium Chloride+ Chloroform+ Menthol	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate: Ammonium chloride is expectorant which increases mucus secretion & should not be given in combination with Chlorpheniramine (an antihistaminic cough suppressant with anti-cholinergic properties) which supresses cough and dries up secretions . 2. Chloroform is more harmful when taken orally compared to inhalation. It is hepatotoxic & cardiotoxic and may cause ventricular fibrillation. 3. Chlorpheniramine & Chloroform, both have CNS depressant effects, which are additive. Therefore, the combination is irrational with potential of causing adverse effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
277	S.O. 981(E)	Chlorpheniramine+ Ammonium Chloride+ Chloroform+ Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 982(E)	Salbutamol+ Choline Theophylinate+ Ambroxol	-	-	-	-	1. Choline theophyllinate has a narrow therapeutic index. Hence, not suitable in FDC as per guidelines. 2. Mucolytic (Ambroxol) alongwith anti-asthmatic drugs is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drugs (Salbutamol &Ccholine theophyllinate) and their adverse effects. 3. Mucolytic (Ambroxol) is not indicated in broncial asthma as per guidelines. 4. Given the superiority of inhaled Salbutamol over oral Salbutamol, oralSsalbutamol is indicted only when inhaled Salbutamol is not available. It is not preferable to have oral Salbutamol in FDC. 5. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
278	S.O. 982(E)	Salbutamol+ Choline Theophylinate+ Ambroxol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 983(E)	Chlorpheniramine+ Codeine phosphate+ Menthol syrup	-	-	-	-	The Subcommittee noted that this FDC was approved pre 1988 as claimed by Sh. Kapil Sibal. However, the appellant did not submit any evidence in this regard. The Subcommittee noted that the FDC of Chlorpheniramine maleate+ Codeine phosphate for dry cough is approved on 10.03.95 by CDSCO. Further the Subcommittee noted that: 1.Codeine and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as this can lead to excessive sedation. 2. There is also a risk of abuse potential in view of Codeine being an ingredient. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
279	S.O. 983(E)	Chlorpheniramine+ Codeine phosphate+ Menthol syrup	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 984(E)	Pseudoephedrine+ Bromhexine	-	-	-	-	1. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
260	S.O. 984(E)	Pseudoephedrine+ Bromhexine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

491

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Akums Drugs	Cetirizine HCl 5mg/5mg + Phenylephrine HCl 10mg/5mg + Paracetamol 325mg/325mg+ Caffeine 25mg/25mg+ Nimesulide BP 100mg/100mg uncoated tablet	Nasal congestion, common cold, rhinorrhoea, fever with common cold, allergic cough and bodyache.	i) Indication mentioned in package insert does not match with Annexure A. Indications mentioned in package insert are: Relief of nasal and sinus congestion,relief of allergic symptoms of the nose or throat due to upper respiratory tract allergies,relief of sinus pain and headache,adjunct with antibacterials in sinusitois,tonsilitis and otitis media. ii) Not Submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Ind Swift	Cetirizine HCL IP 5mg+ Phenylephrine HCl IP 5mg+ Paracetamol IP 325mg+ Caffeine Anhydrous IP 30mg+ Nimesulide BP 100mg uncoated tablet	• Relief of nasal and sinus congestion. • Relief of allergic symptoms of the nose or throat due to upper respiratory tract allergies. • Relief of sinus pain and headache. • Adjunct with antibacterials in sinusitis, tonsillitis, and otitis media	i) Indication for FDC not mentioned but the firm has submitted indication for individual active ingredients. ii) Not submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Magnet Lab	Cetirizine HCL IP 5mg+ Phenylephrine HCl IP 10mg+ Paracetamol IP 325mg+ Caffeine Anhydrous IP 25mg+ Nimesulide 100mg uncoated tablet	Used in treatment of symptoms associated with common cold and allergic rhinitis (i.e. fever, sneezing, nasal congestion, headache, running nose)	i) Same as Annexure A ii) Not submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Mascot Healthcare	Cetirizine HCl IP 5mg+ Phenylephrine HCl IP 10mg + Paracetamol IP 325mg+ Caffeine IP 25mg+ Nimesulide BP 100mg uncoated tablet	Relief of nasal and sinus congestion. Relief of allergic symptoms of the nose or throat due to upper respiratory tract allergies. Relief of sinus pain and headache. Adjunct with antibacterial in sinusitis, tonsillitis and otitis media.	i) Indication for FDC not mentioned. ii) Not submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Windlas Biotech	Cetirizine HCl IP 5mg+ Phenylephrine HCl IP 10mg + Paracetamol IP 325mg+ Caffeine IP 25mg+ Nimesulide BP 100mg film coated tablet	For relief of irritating and troublesome cough fever and headache.	i) Same as Annexure A ii) Not relevant.	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Tirupati Medicare	Cetirizine HCl IP 5mg+ Phenylephrine HCl IP 10mg + Paracetamol IP 325mg+ Caffeine IP 25mg+ Nimesulide BP 100mg film coated tablet	Used in for treatment of allergy, nasal congestion, fever and pain.	i) Temporarily relieve symptoms due to allergic rhinitis or other upper respiratory tract allergies,temperarily relieves these symptoms due to common cold or flu, relief of sinus pain and headache,Adjunct with antibacterials in sinusitis,tonsillitis and otitis media. ii) Not relevant.	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Ravian Life Sciences	Cetirizine HCl IP 5mg+ Phenylephrine HCl IP 10mg+ Paracetamol IP 325mg+ Caffeine IP 25mg+ Nimesulide IP 100mg uncoated tablet	Allergic rhinitis, sneezing, nasal decongestion , pain and fever, sinusitis, tonsillitis, adjunct to antibiotic in URTI	i) Not submitted ii) Not submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Ravian Life Sciences	Cetirizine IP 5mg+ Phenylephrine HCl IP 10mg+ Paracetamol IP 325mg+ Caffeine IP 25mg+ Nimesulide IP 100mg uncoated tablet	Allergic cough, sinusitis, seasonal flu, cough and common cold.	i) Not submitted ii) Not submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Mefro Organic Ltd.	Cetirizine IP 5mg+ Phenylephrine HCl IP 10mg+ Paracetamol IP 325mg+ Caffeine IP 25mg+ Nimesulide IP 100mg uncoated tablet	Not submitted	i) Not submitted ii) Not submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 985(E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Horizon Bioceuticals	Cetirizine HCL IP 5mg+ Phenylephrine HCl IP 5mg+ Paracetamol IP 325mg+ Caffeine Anhydrous IP 25mg+ Nimesulide BP 100mg uncoated tablet	Mutli symptoms cold relief such as flu, fever congestion stuffy nose and decongestant no drowsy.	i) Same as Annexure A ii) Not submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 985 (E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	DM Pharma	Cetirizine HCl IP 5mg+ Phenylephrine HCl IP 10mg+ Paracetamol IP 325mg+ Caffeine IP 25mg+ Nimesulide BP 100mg film coated tablet	Common cold, cough, allergic rhinitis, fever, body aches and headaches associated with the cold.	i) Same as Annexure A ii) Not submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 985 (E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	Meridian Medicare	Cetirizine HCl IP 5mg+ Phenylephrine HCl IP 10mg+ Paracetamol IP 325mg+ Caffeine IP 25mg+ Nimesulide BP 100mg tablet	Analgesic, antipyretic	i) Not submitted ii) Not submitted	1. Pharmacodynamically inappropriate FDC because Paracetamol alone has antipyretic and analgesic activity and hence there is no need to add Nimesulide which has adverse effects including hepatotoxicity. 2.Pharmacokinetically incompatible: Cetirizine is given once a day whereas Nimesulide is twice a day and Paracetamol is given four times a day. 3.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine, and Nimesulide are associated with increased gastric secretion leading to potential risk of gastric ulcer. 5. Patients may not need all the five ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 6. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
281	S.O. 985 (E)	Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 986(E)	Dextromethorphan + Cetirizine + Guaifenesin+ Ammonium Chloride	Mascot	Dextromethorphan Hbr 10mg+ Ctrizine HCL 5 mg+ Gauiphenesin 50 mg+ Ammonium Chloride 60 mg per 5 ml syrup	Sneezing, Cough and Cold	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Cough, Rhinitis, Bronchitis ii. Not Submitted	1. Dextromethorphan and Cetirizine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 2. Pharmacodynamically antagonistic and hence inappropriate: Expectorants like Guaiphenesin and Ammonium Chloride increase secretions whereas Dextromethorphan is cough suppressant and so hampers the expulsion of secretions. 3. The FDC is pharmacokinetically incompatible: Cetirizine is given once a day and Dextromethorphan is to be given QID. 4.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
282	S.O. 986(E)	Dextromethorphan + Cetirizine + Guaifenesin+ Ammonium Chloride	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 987(E)	Ambroxol + Salbutamol + Choline Theophyllinate + Menthol	-	-	-	-	1. Choline theophyllinate has a narrow therapeutic index. Hence, not suitable in FDC as per guidelines. 2. This combination is not as per standard therapeutic guidelines. 3. Mucolytic (Ambroxol) is not indicated in bronchial asthma. 4. Use of mucolytic alongwith anti-asthmatic drugs is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drugs (salbutamol, choline theophyllinate) and their adverse effects. 5. Given the superiority of inhaled salbutamol over oral salbutamol, oral salbutamol is indicted only when inhaled salbutamol is not available. It is not preferable to have oral salbutamol in FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
283	S.O. 987(E)	Ambroxol + Salbutamol + Choline Theophyllinate + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 988(E)	Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine	Indoco Remedies	Paracetamol IP 325mg+ Phenylephrine HCl IP 10mg+ chlorpheniramine Maleate IP 2mg+ Guaiphenesin IP 100mg+ Ambroxol HCl IP 30mg film coated tablet	Common cold associated with productive cough & body ache	i) Common cold,allergic rhinits associated with cough ii) Not Approved	1. There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Ambroxol is a mucolytic agent and both the latter drugs increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC as patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 988(E)	Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine	Puro Pharma	Paracetamol IP 500mg+ Phenylephrine HCl IP 10mg+ Chlorpheniramine Maleate IP 2mg+ Guaiphenesin IP 100mg+ Ambroxol HCl IP 30mg film coated tablet	Upper respiratory tract infections associated with cough cold fever and bodyache.	i) Same as annexure A ii) Not Approved	1. There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Ambroxol is a mucolytic agent and both the latter drugs increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC as patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 988(E)	Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine	Centaur	Paracetamol IP 500mg+ Phenylephrine HCl IP 10mg+ chlorpheniramine Maleate IP 2mg+ Guaiphenesin IP 100mg+ Ambroxol HCl IP 30mg film coated tablet	In the treatment of upper respiratory tract infections associated with cough cold fever and bodyache.	i) Same as Annexure A ii) Not submitted	1. There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Ambroxol is a mucolytic agent and both the latter drugs increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC as patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 988(E)	Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine	Akums Drugs	Paracetamol IP 325mg+ Chlorpheniramine Maleate IP 2mg+ Ambroxol HCl IP 30mg + Guaifenesin IP 100mg + Phenylephrine HCl IP 10mg uncoated tablet	Upper respiratory tract infections associated with cough cold fever and bodyache.	i) same as Annexure A ii) Not submitted	1. There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Ambroxol is a mucolytic agent and both the latter drugs increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC as patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 988(E)	Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine	IPCA Laboratories	Paracetamol IP 500mg+ Chlorpheniramine Maleate IP 2mg+ Ambroxol HCl IP 30mg+ Guaiphenesin 100mg+ Phenylephrine HCl IP 10mg tablet	Symptomatic relief of cold cough and fever associated with respiratory tract infections.	i) Same as Annexure A ii) Not submitted	1. There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Ambroxol is a mucolytic agent and both the latter drugs increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC as patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 988(E)	Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine	Wings Pharmaceuticals Pvt. Ltd.	Paracetamol IP 325mg+ Chlorpheniramine Maleate IP 2mg+ Ambroxol HCl IP 30mg+ Guaiphenesin 100mg+ Phenylephrine HCl IP 10mg tablet	Common cold, allergic rhinitis, urticaria, hay fever, runny nose, sneezing, flu & sinusitis	Not submitted	1. There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Guaiphenesin is an expectorant and Ambroxol is a mucolytic agent and both the latter drugs increase secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. There is no rationale in combining five ingredients in single FDC as patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
284	S.O. 988(E)	Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 989(E)	Chlorpheniramine + Vasaka + Tolubalsam + Ammonium Chloride + Sodium Citrate + Menthol	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate (Vasaka, Tolubalsam, Ammonium chloride, Sodium Citrate are mucolytic/expectorant whereas Chlorpheniramine is anti histaminic, cough supressant and anti cholinergic which dries up mucous secretion). 2. There is no rationale for six ingredients in ths FDC. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
285	S.O. 989(E)	Chlorpheniramine + Vasaka + Tolubalsam + Ammonium Chloride + Sodium Citrate +	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 990(E)	Bromhexine + Cetrizine + Phenylephrine + Guaifenesin + Menthol	Wings	Each 5ml contains: Bromhexine Hydrochloride 4mg + Menthol 1mg + Cetirizine Hydrochloride 2.5mg + Phenylephrine 5mg + Guaiphenesin 50mg	For productive cough and cold	i. Indications same as Annexure A ii As per Annexure A firm has mentioned that it is marketed and approved in India.	1 . Pharmacokinetically incompatible: Cetirizine is given once a day whereas other ingredients are given three to four times a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
286	S.O. 990(E)	**Bromhexine + Cetrizine + Phenylephrine + Guaifenesin + Menthol**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 991(E)	Dextromethorphan + Ambroxol + Ammonium Chloride + Chlorpheniramine + Menthol	-	-	-	-	1. Pharmacodynamicallyantagonistic and hence inappropriate: Ambroxol and Ammonium Chloride are mucolytic and expectorant whereas Chlorpheniramine sipresses cough and dries up secretion. 2. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination will lead to excessive sedation. 3. This combination is not as per standard therapeutic guidelines. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
287	S.O. 991(E)	Dextromethorphan + Ambroxol + Ammonium Chloride + Chlorpheniramine + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 992(E)	Dextromethorphan + Phenylephrine + Cetirizine + Zinc + Menthol	-	-	-	-	1. Pharmacokinetically incompatible (Dextromethorphan is given four times a day whereas cetirizine is given once a day). 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Dextromethorphan and Cetirizine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
288	S.O. 992(E)	Dextromethorphan + Phenylephrine + Cetirizine + Zinc + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 993(E)	Terbutaline + N-Acetyl L-Cysteine + Guaifenesin	-	-	-	-	1. As per guidelines there is no role of mucolytics in ashthma. 2. There is no therapeutic justification for the ingredients to be combined. 3. This FDC is not as per the current therapeutic guidelines 4. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessarily to the antiasthamatic drug (terbutaline) and its adverse effect. There is no sound scientific/ clinical evidence/ justification for the FDC.
289	S.O. 993(E)	Terbutaline + N-Acetyl L-Cysteine + Guaifenesin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 994(E)	Calcium Gluconate + Levocetirizine	-	-	-	-	1. Pharmacodynamically inappropriate: no rationale for combining calcium gluconate with an anti histaminic agent. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
290.	S.O. 994(E)	Calcium Gluconate + Levocetirizine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 995(E)	Paracetamol + Levocetirizine+ Pseudoephedrine	-	-	-	-	1. Pharmacokinetic incompatibility (Paracetamol is given 4 times a day & Levocetirizine is given once a day.) 2. Patients may need only one ingredient and use of this FDC may lead to unnecessary exposure to other ingredients since all symptoms may not exist at the same time. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
291	S.O. 995(E)	Paracetamol + Levocetirizine + Pseudoephedrine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 996(E)	Salbutamol + Choline Theophylinate + Carbocisteine	-	-	-	-	1. Choline Theophyllinate has a narrow therapeutic index. Hence as per guidelines not suitable for combining in FDC. 2. As per Guidelines there is no role of mucolytics (Carbocisteine) in ashthma. 3. This FDC is not as per the current therapeutic guidelines. 4. Use of mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessarily to the anti asthma drug Salbutamol and its adverse effect. There is no sound scientific/ clinical evidence/ justification for the FDC.
292	S.O. 996(E)	Salbutamol + Choline Theophylinate + Carbocisteine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S. O. 997(E)	Chlorpheniramine + Vitamin C	Retort Laboratories	Chlorpheniramine maleate IP 2mg+ Ascorbic Acid IP 30mg per 5ml liquid oral	All allergic conditions due to various etiology. Perennial and seasonal allergic rhinitis and other allergic symptoms.Hay fever. Vasomotor rhinitis. Urticaria. Food allergies, drug and serum reactions, , pruritus, Insect bites.	i) Symptomatic control of allergic conditions responsive to ant-histamines. For e.g. Hay fever, Vasomotor Rhinitis, Urticaria, Food allergies, Drug and Serum reactions, pruritis & insect bites. Ii) Not submitted	1. Pharmacodynamically inappropriate FDC as there is no rationale for combining Vitamin C with an anti- histaminic agent. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
293	S. O. 997(E)	Chlorpheniramine + Vitamin C	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

514

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S. O. 998(E)	Calcium Gluconate + Chlorpheniramine + Vitamin C	Retort Laboratories	Chlorpheniramine maleate IP 4mg+ Ascorbic Acid IP 50mg+ Calcium Gluconate IP 500mg uncoated tablet	All allergic conditions due to various Etiology, Perennial and seasonal allergic rhinitis and other allergic symptoms, Hay fever, Vasomotor rhinitis, Urticaria, food allergies, drug and serum reactions, pruritis, insect bites.	i. The symptomatic control of allergic conditions responsive to antihistamines eg., Hay Fever, Vasomotor rhinitis, Urticaria, angioneurotic oedema, food allergies, drug and serum reactions, pruritis and insect bites. Ii. Not Submitted	1. Pharmacodynamically inappropriate as there is no rationale for combining Calcium Gluconate and Vitamin C with an anti- histaminic agent. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
294	S. O. 998(E)	Calcium Gluconate + Chlorpheniramine + Vitamin C	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 999(E)	Chlorpheniramine+ Paracetamol + Pseudoephedrine + Caffeine	-	-	-	-	1. Pharmacodynamically inappropriate FDC as this combination is not as per standard therapeutic guidelines. 2. Patients may not need all the ingredients simultaneously and use of FDC may lead to unnecessary exposure to multiple medicines. There is no sound scientific/ clinical evidence/ justification for the FDC.
295	S.O. 999(E)	Chlorpheniramine+ Paracetamol + Pseudoephedrine + Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1000(E)	Guaifenesin+ Bromhexine+ Chlorpheniramine+ Phenylephrine+ Paracetamol+ Serratiopeptidase (as enteric coated granules)10000 SP Units	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate: Guaiphenesin and Bromhexine are expectorant/mucolytic agents which increase mucus secretion and should not be given in combination with Chlorpheniramine which is a cough supressant which hampers expulsion of secretions. Moreover, it dries up secretions. 2.There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may need all the six ingredients and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
296	S.O. 1000(E)	Guaifenesin+ Bromhexine+ Chlorpheniramine+ Phenylephrine+ Paracetamol+ Serratiopeptidase (as enteric coated granules)10000 SP Units	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1001(E)	Paracetamol + Pheniramine	-	-	-	-	1. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
297	S.O. 1001(E)	Paracetamol + Pheniramine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

516

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O.1002(E)	Betamethasone +Fusidic Acid +Gentamycin +Tolnaftate +Iodochlorhydroxyquinoline(ICHQ)	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining three antimicrobials (Fusidic acid, Gentamicin, Iodochlorhydroxyquinolone), antifungal (Tolnaftate), steroid (Betamethasone) in the FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
298	S.O.1002(E)	Betamethasone +Fusidic Acid +Gentamycin +Tolnaftate +Iodochlorhydroxyquinoline(ICHQ)	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

519

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O.1003(E)	Clobetasol +Ofloxacin +Miconazole +Zinc Sulphate	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Miconazole), high potency steroid (Clobetasol), anti-bacterial (Ofloxacin) & zinc sulphate in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
299	S.O.1003(E)	Clobetasol +Ofloxacin +Miconazole +Zinc Sulphate	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O.1004(E)	Clobetasole +Gentamicin +Miconazole +Zinc Sulphate	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Miconazole), high potency steroid (Clobetasol), anti-bacterial (Gentamicin) & zinc sulphate in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
300	S.O.1004(E)	Clobetasole +Gentamicin +Miconazole +Zinc Sulphate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1005(E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	Akums Drugs	Levocetirizine HCl IP 2.5mg/5mg+ Ambroxol HCl IP 60mg/30mg+ Phenylephrine HCl IP 5mg/5mg + Paracetamol IP 500mg/325mg tablet	For relief from symptoms of common cold and nasal congestion and associated fever due to allergic reactions.	i) Same as Annexure A ii) Not submitted	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1005(E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	Akums Drugs	Levocetirizine HCl IP 2.5mg/2.5mg + Ambroxol HCl IP 60mg/60mg+ Phenylephrine HCl IP 5mg/10mg + Paracetamol IP 500mg/325mg tablet	It is indicated for cold & decongestant	i) Analgesic,antipyretic and Decongestant.Indicated for cold and flu relief ii) Not submitted	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1005(E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	Akums Drugs	Levocetirizine HCL IP 2.5mg+ Ambroxol HCl IP 30mg+ Phenylephrine HCl IP 5mg+ Paracetamol IP 250mg per 5ml syrup	Treatment of allergies, hay fever, cold, cough, urticaria and sinus headache. Syrup is dosage form for paediatric use in a palatable taste.	i) Same as Annexure A ii) Not submitted	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1005(E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	Cipla Ltd.	Levocetirizine HCl IP 5mg+ Phenylephrine Hcl IP 5mg+ Ambroxol HCl 30mg+ Paracetamol IP 325mg uncoated tablet	Chronic sinusitis, rhinitis with fever (Flu like symptoms), nasal discharge, sore throat and wheezing	i) Same as Annexure A ii) Not submitted	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1005(E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	SunDyota Numandis	Levocetirizine 2.5mg+ Ambroxol 30mg+ Phenylephrine 10mg+ Paracetamol 325mg tablet	Cold and congestion associated with fever and cough in adults.	i) Indication provided in package insert is different than above- It is stated as common cold and allergic rhinitis. ii) Not Available	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1005(E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	Windlas Biotech	Levocetirizine 2.5mg+ Ambroxol 30mg+ Phenylephrine 10mg+ Paracetamol 325mg tablet	Cold and congestion associated with fever and cough in adults.	i) Indication in package insert is different from above- It is stated as indicated for common cold and allergic rhinitis. ii) Not Available	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1005(E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	Skymap Pharmaceutical	Levocetirizine 2.5mg+ Ambroxol 60mg+ Phenylephrine Hcl 5mg+ Paracetamol 325mg uncoated tablet	Anti cough	i) Not submitted ii) Data not available.	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1005(E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	Varav Biogenesis/ Horizon Bioceuticals	Levocetirizine HCL IP 5mg+ Ambroxol HCl IP 60mg+ Phenylephrine HCl IP 10mg+ Paracetamol IP 500mg uncoated tablet	Antiallergic, expectorant, analgesic and decongestant	i) Same As Annexure A ii) Not submitted	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1005 (E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	DM Pharma	Levocetirizine HCL IP 2.5mg+ Ambroxol HCl IP 60mg+ Phenylephrine HCl IP 5mg+ Paracetamol IP 325mg uncoated tablet	Common Cold, Allergic Rhinitis, Cough, Fever and aches associated with cough.	i) Same as Annexure A ii) Not submitted	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1005 (E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	Meridian Medicare	Levocetirizine HCL IP 2.5mg+ Ambroxol HCl IP 30mg+ Phenylephrine HCl IP 5mg+ Paracetamol IP 325mg	Anti-allergic, Analgesic	i) Not submitted ii) Not submitted	1. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day whereas Levocetirizine is given once a day. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3.This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
301	S.O. 1005 (E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O.1006(E)	Permethrin + Cetrimide + Menthol	Lifestar	Permethrin 1.0%w/w+Cetrimide IP 0.5%w/w+Menthol IP 1.0%w/w soap	Treatment and prevention of head lice infestation associated with secondary bacterial infection, Prevention of scabies.	i.indication same as annexure-A ii. Not approved	1.Menthol is not necessary for the therapeutic indication stated. 2. There is no data provided to support use of this FDC in the indication of prevention of scabies and pediculosis. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1006(E)	Permethrin + Cetrimide + Menthol	Psychotropics India Ltd	Permethrin + Cetrimide + Menthol	NA	i) Not submitted ii) Not submitted	1.Menthol is not necessary for the therapeutic indication stated. 2. There is no data provided to support use of this FDC in the indication of prevention of scabies and pediculosis. There is no sound scientific/ clinical evidence/ justification for the FDC.
302	S.O. 1006(E)	Permethrin + Cetrimide + Menthol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O.1007(E)	Beclomethasone +clotrimazole +neomycin +iodochlorohydroxyquinone	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Clotrimazole), potent steroid (Beclomethasone) & two anti-bacterials (Iodochlorohydroxyquinolone, Neomycin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
303	S.O.1007(E)	Beclomethasone +clotrimazole +neomycin +iodochlorohydroxyquinone	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	I. Indicaiton as per package insert II. If marketing any where	
	S.O. 1008(E)	Neomycin + Doxycycline	-	-	-	-	1. Pharmacokinetic mismatch (Dosing frequency of the two drugs is different Neomycin is given 4 times a day white Doxycycline is given once a day). 2. There is no sound scientific/clinical evidence to support the use of this FDC in any clinical condition. 3. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
304	S.O. 1008(E)	Neomycin + Doxycycline	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O.1009(E)	Ciprofloxacin HClIP eq. to Ciprofloxacin FluocinoloneAcetonide IP Clotrimazole IP Neomycin Sulphate IP	Blessing Healthcare	Ciprofloxacin HCl IP eq. to Ciprofloxacin 0.5%w/w+ Fluocinolone Acetonide IP 0.025%w/w+ Clotrimazole IP 1.0%w/w+ Neomycin Sulphate IP 0.5%w/w cream+ Chlorocresol	The firm has mentioned "Warning" as an indication in Annexure A.	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Treatment of inflamed conditions of the skin such as eczema and dermatitis which may be caused by infection with certain fungi and bacteria. It is effective in relief of inflammatory and pruritic dermatoses. It is also used to treat the itching, redness, crusting, scaling, inflammation and discomfort of various skin conditions. ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Clotrimazole), potent steroid (Fluocinolone) & two anti-bacterials (Ciprofloxacin, Neomycin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O.1009(E)	Ciprofloxacin HClIP eq. to Ciprofloxacin FluocinoloneAcetonide IP Clotrimazole IP Neomycin Sulphate IP	Laborate Pharmaceuticals	Ciprofloxacin HCl IP eq. to Ciprofloxacin 0.5%w/w+ Fluocinolone Acetonide IP 0.025%w/w+ Clotrimazole IP 1.0%w/w+ Neomycin Sulphate IP 0.5%w/w cream+ Chlorocresol	Used for treatment of inflamed conditions of the skin such as eczema and dermatitis which may b caused by infection with certain fungi and bacteria. Effective in relief of inflammatory and pruritic dermatoses. Used to treat the itching, redness, crusting, scaling, inflammation and discomfort of various skin conditions.	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: The topical treatment of superficial bacterial infections, cutaneous candidiasis and dermatological conditions known to respond to topical steroid therapy when threatened or complicated by bacterial orcandidal superinfections. These include; atopic aczema, contact eczema, follicular eczema, infantil eczema, anogenital pruritis (anal and vulval pruritis), nummular eczema, post traumatic infective eczema, seborrhoeic or flexural eczema, nuerodermatitis, psoriasis. ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Clotrimazole), potent steroid (Fluocinolone) & two anti-bacterials (Ciprofloxacin, Neomycin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
305	S.O.1009(E)	Ciprofloxacin HClIP eq. to Ciprofloxacin FluocinoloneAcetonide IP Clotrimazole IP Neomycin Sulphate IP	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and bearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O.1010(E)	Clobetasol +Ofloxacin +Ketoconazole +Zinc Sulphate	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Ketoconazole), high potency steroid (Clobetasol), anti-bacterial (Ofloxacin) & zinc sulphate in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
306	S.O.1010(E)	Clobetasol +Ofloxacin +Ketoconazole +Zinc Sulphate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O.1011(E)	Betamethasone Valerate +Gentamicin Sulphate equivalent to Gentamicin base +Tolnaftate +Iodochlorhydroxyquinoloine(Clioquinol)	Universal Twin Labs	Betamethasone Valerate IP 0.50mg+Gentamicin sulphate IP eq. to Gentamicin 1.0mg+Tolnaftate IP 15.00mg +Iodochlorhydroxyquinoline (Ciloquinol) IP 15.00mg cream	Anti-inflammatory antibacterial antibiotic antifungal and bacteriostatic	Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Inflammatory manifestations of corticosteroid-responsive dermatoses when complicated bysecondary infection caused by organisms sensitive to the components of this dermatologicpreparation or when the possibility of such infection is suspected. ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Tolnaftate), steroid (Betamethasone) & two anti-bacterials (Gentamicin, Iodochlorohydroxyquinolone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
307	S.O.1011(E)	Betamethasone Valerate +Gentamicin Sulphate equivalent to Gentamicin base +Tolnaftate +Iodochlorhydroxyquinoloine(Clioquinol)	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1012(E)	Clobetasol Propionate BP+ Gentamicin Sulphate IP Equivalent To GentamicinTolnaftate IP +TolnaftateIP+ Idochlorhydroxyquinone IP + Ketoconazole IP	NEM Laboratories	Clobetasol Propionate 0.5mg+Gentamicin 1.0mg+Tolnaftate 10.0mg+Idochlorhydroxyquinone 10.0mg+Ketoconazole 20.0mg cream	itching , fungal infection , rashes,skin rashes,eczema,dermatitis and psoriasis.	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: For the topical treatment of mixed infections like Itching, Fungal Infection, Rashes, Eczema, Dermatitis, Psoriasis caused by organisms that are sensitive to the components of this products or when the possibility of such mixed infection is suspected. ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antibiotic (Gentamicin), two antifungals (Tolnaftate, Ketoconazole), high potency steroid (Clobetasol) & anti- bacterial (Iodochlorhydroxyquinone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1012(E)	Clobetasol +Gentamicin +Tolnaftate +Idochlorhydroxyquinone +Ketoconazole	Universal Twin Labs	Clobetasol Propionate USP 0.05%w/w+Gentamicin sulphate IP eq. to gentamicin sulpahte 0.10%w/w+Tolnaftate IP 1.00%w/w+Idochlorhydroxyquinone (Ciloquinol) IP 1.00%w/w+Ketoconazole IP 2.00%w/w cream	Anti-inflammatory antibacterial antibiotic antifungal and bacteriostatic	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Inflammatory manifestations of corticosteroid-responsive dermatoses when complicated bysecondary infection caused by organisms sensitive to the components of this dermatologicpreparation or when the possibility of such infection is suspected. ii. Not approved	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antibiotic (Gentamicin), two antifungals (Tolnaftate, Ketoconazole), high potency steroid (Clobetasol) & anti- bacterial (Iodochlorhydroxyquinone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1012(E)	Clobetasol +Gentamicin +Tolnaftate +Idochlorhydroxyquinone +Ketoconazole	Avni Pharma	Clobetasol Propionate IP 0.05%w/w+Gentamicin Sulphate IP 0.1%w/w+Tolnaftate IP 1.0%w/w+Idochlorhydroxyquinone IP 1.0%w/w+Ketoconazole IP 2.0%w/w+Chlorocresol IP 0.1%w/w (Preservative) cream	As directed by physician	i.Peakge insert was not submitted. Ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antibiotic (Gentamicin), two antifungals (Tolnaftate, Ketoconazole), high potency steroid (Clobetasol) & anti- bacterial (Iodochlorhydroxyquinone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1012(E)	Clobetasol +Gentamicin +Tolnaftate +Idochlorhydroxyquinone +Ketoconazole	Blessing Healthcare	Clobetasol Propionate IP 0.05%w/w+Gentamicin Sulphate IP 0.1%w/w+Tolnaftate IP 1.0%w/w+Idochlorhydroxyquinone IP 1.0%w/w+Ketoconazole IP 2.0%w/w cream	None	Indication mentioned in package insert is different from above. Indications mentioned in package insert are for individual ingredients: Clobetasol is used in the treatment of severe allergic reaction, allergic disorders and skin disorders. Clobetasol is a highly potent corticosteroid. It reduces the actions of chemicals in the body that cause inflammation. Gentamicin is used in the treatment of bacterial infections. Gentamicin is an antibiotic it kills bacteria by inhibiting synthesis of essential proteins, required by bacteria to carry out vital functions. Tolnaftate is used in the treatment of skin infections and fungal infections. Tolnaftate stops the growth of fungus by preventing them from making their protective covering. Clioquinol (Idochlorhydroxyquinone) is used in treatment of skin infections, fungal and bacterial infection of external ear.	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antibiotic (Gentamicin), two antifungals (Tolnaftate, Ketoconazole), high potency steroid (Clobetasol) & anti- bacterial (Iodochlorhydroxyquinone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
						Clioquinol belongs to a category of drugs called as hydeoxyquinoline antifungal agents. It acts by interaction with DNA synthesis thus killi98ng the fungi that are responsible for cause the infection. Ketaconazole is used in the treatment of fungal infections. Ketaconazole is an antifungal medication. It stops the growth of fungus by prevent8ing them from forming their own protective covering which is required for their survival in the human. ii. Not suibmitted	

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1012(E)	Clobetasol +Gentamicin +Tolnaftate +Idochlorhydroxyquinone +Ketoconazole	Avni Pharma	Clobetasol Propionate IP 0.05%w/w+Gentamicin Sulphate IP eq. to Gentamicin 0.1%w/w+Tolnaftate IP 1.0%w/w+Idochlorhydroxyquinone IP 1.0%w/w+Ketoconazole IP 2.0%w/w+Chlorocresol IP 0.1%w/w (Preservative) cream	As directed by physician	i.Peakage insert was not submitted ii.Not submitted.	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antibiotic (Gentamicin), two antifungals (Tolnaftate, Ketoconazole), high potency steroid (Clobetasol) & anti- bacterial (Iodochlorhydroxyquinone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1012(E)	Clobetasol +Gentamicin +Tolnaftate +Idochlorhydroxyquinone +Ketoconazole	Avni Pharma	Clobetasol Propionate IP 0.05%w/w+Gentamicin Sulphate IP eq. to Gentamicin 0.1%w/w+Tolnaftate IP 1.0%w/w+Idochlorhydroxyquinone IP 1.0%w/w+Ketoconazole IP 2.0%w/w+Chlorocresol IP 0.1%w/w (Preservative) cream	As directed by the physician	i.Peakage insert was not submitted ii.Not submitted.	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antibiotic (Gentamicin), two antifungals (Tolnaftate, Ketoconazole), high potency steroid (Clobetasol) & anti- bacterial (Iodochlorhydroxyquinone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1012(E)	Clobetasol +Gentamicin +Tolnaftate +Idochlorhydroxyquinone +Ketoconazole	Varav Biogenesis	Each gm contains: Clobetasol Propionate 0.5mg+Gentamicin 1.0mg+Tolnaftate 10.0mg+Idochlorhydroxyquinone 10.0mg+Ketoconazole 20.0mg cream	Topical corticosteroid /anti bacterial/ anti fungal agent	i.Indications mentioned in package insert are: antifungal, antibacterial andanti-inflammatory ii.Not submitted.	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antibiotic (Gentamicin), two antifungals (Tolnaftate, Ketoconazole), high potency steroid (Clobetasol) & anti- bacterial (Iodochlorhydroxyquinone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1012(E)	Clobetasol +Gentamicin +Tolnaftate +Idochlorhydroxyquinone +Ketoconazole	Unimarck Pharma (India) Pvt Ltd	Each gm contains: Clobetasol Propionate 0.5mg+Gentamicin 1.0mg+Tolnaftate 10.0mg+Idochlorhydroxyquinone 10.0mg+Ketoconazole 20.0mg cream	Skin fungal infection	i.Not submitted ii.As per firm, FDC marketed and approved in India.	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antibiotic (Gentamicin), two antifungals (Tolnaftate, Ketoconazole), high potency steroid (Clobetasol) & anti- bacterial (Iodochlorhydroxyquinone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC for the stated indications. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
308	S.O. 1012(E)	Clobetasol +Gentamicin +Tolnaftate +Idochlorhydroxyquinone +Ketoconazole	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1013(E)	Allantoin+Dimethieone+ Urea+Propylene+Glyceri n+Liquid paraffin	Fourrts India	Allantoin IP 0.2%w/w+Dimethieone IP 1%w/w+Urea IP 10%w/w+Propylene Glycol IP 5%w/w+Glycerin IP 5%w/w+Liquid paraffin IP 8%w/w cream	For burning foot syndrome and moisturising cream for diabetic patients.	i.Indication same as annexure-A ii. Not approved	The appellant provided data on individual ingredient, however did not provide any data for therapeutic advantage that is achieved by combination of six ingredients in this FDC for the stated indications. There is no sound scientific/ clinical evidence/ justification for the FDC.
309	S.O. 1013(E)	Allantoin+Dimethieone +Urea+Propylene+Gly cerin+Liquid paraffin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1014(E)	Acriflavine BP 63 +Thymol IP +Cetrimide IP	DM Pharma	Acriflavine BP 63 0.12g+Thymol IP 5.00mg+Cetrimide IP 0.50gm per 100gm cream	Wound	i.Indication same as annexure-A ii. Not submitted.	The sub-committee noted that this FDC was earlier discussed by previous "10 expert Committee" on 22.8.2014 and the comments were as under: "Firm could not present any supporting data in respect of the rationality of the FDC. Moreover, the FDC is also not approved anywhere in the world. Hence, the committee did not recommend." The sub-committee concured with the above recommendations and noted that: 1. No therapeutic advantage is achieved by addition of Thymol and/or Cetrimide in this FDC. There is no convincing scientific/ clinical evidence/ justification for the FDC.
310	S.O. 1014(E)	Acriflavine BP 63 +Thymol IP +Cetrimide IP	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1015(E)	Betamethasone +Neomycin +Tolnaftate +IodoChloroHydroxyQuinoline +Cholorocresol	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Tolnaftate), steroid (Betamethasone) & two anti-bacterials (Neomycin, Iodochlorohydroxyquinolone) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
311	S.O. 1015(E)	Betamethasone +Neomycin +Tolnaftate +IodoChloroHydroxyQuinoline +Cholorocresol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1016(E)	clobetasol +Neomycin +Miconazole +Clotrimazole	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Miconazole, Clotrimazole), high potency steroid (Clobetasol) & anti-bacterial (Neomycin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
312	S.O. 1016(E)	clobetasol +Neomycin +Miconazole +Clotrimazole	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1017(E)	Ketoconazole +Tea Tree oil +Allantion +zinc Oxide +Aloe Vera +Jojoba oil +Lavander oil +Soap noodles	-	-	-	-	This FDC has no defined therapeutic area and patient population. There is no scientific/ clinical evidence/ justification for the FDC.
313	S.O. 1017(E)	Ketoconazole +Tea Tree oil +Allantion +zinc Oxide +Aloe Vera +Jojoba oil +Lavander oil +Soap noodles	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1018(E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Franco-Indian	Clobetasol Propionate USP 0.05%w/w+Ofloxacin IP 0.75%w/w +Ornidazole IP 2.00%w/w+Terbinafine HCl BP 1.00%w/w+Methyl Paraben IP 0.20%w/w+Propyl Paraben IP 0.02%w/w (as preservative)	□ Mixed and complicated Fungal, Protozoal & Bacterial infections □ Mild to moderate Vaginitis □ Candidiasis and Trichomonas Infection □ Pruritis Vulvae □ Inflammatory Dermatological disorders superadded with bacterial and or superficial fungal infection At the time of hearing, the appellant stated that they would like to change the indication to: "Steroid responsive dermatoses, which do not respond satisfactorily to less active steroids where secondary bacterial and fungal infection is present or suspected."	i.Indication same as Annexure-A ii.Not submitted.	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Mankind Pharma	Clobetasol Propionate 0.5%w/w+Ofloxacin 0.75%w/w+Ornidazole 2%w/w+Terbinafine 1%w/w cream	Mixed infections of various etiology	i.Indication same as Annexure-A ii.Not submitted.	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A			i) Indication as per package insert ii) If marketing any where	Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)		
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Laborate Pharmaceuticals	Clobetasol Propionate IP 0.05%w/w+Ofloxacin IP 0.75%w/w +Ornidazole IP 2.00%w/w+Terbinafine HCl BP 1.00%w/w+Mehyl Paraben IP 0.2%w/w+Propyl Paraben IP 0.04%w/w (as preservative) cream	Antifungal, antibacterial, anti allergic, anti protzoal	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Fungal infections, skin infections, bacterial infections, redness, itching, dryness and swelling of scalp,redness, itching, dryness and swelling of skin, psoriasis, urinary tract infection, respiratory infection, soft tissue infections, sexually transmitted infections, eye and ear infection,, protozoan infections, infections during surgical procedures. ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Avni Pharma	Clobetasol Propionate IP 0.05%w/w+Ofloxacin IP 0.75%w/w+Ornidazole IP 2.0%w/w+Terbinafine HCl BP 0.1%w/w+Chlorocresol (as preservative) IP 0.1%w/w cream	As directed by physician	i. Not submitted. ii. Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Akums Drugs	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 0.05%w/vw+ Clobetasol Propionate BP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.02%w/w cream	Inhibits most fungi pathogenic to man	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: Inhibits most fungi pathogenic to man, treat bacteria that infect inflamed skin, reduces inflammation and relieves itch. ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	I) Indication as per package insert II) If marketing any where	
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Coral Laboratories	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 0.05%w/vw+ Clobetasol Propionate BP 0.05%w/w cream	Used for mixed skin infections, dermatitis & eczemas, tinea infections, candidiasis & trichomonas infections, mild to moderate vaginitisand pruritus vulvae.	i.Pacakge insert not submitted. ii.Not submitted.	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Ind-Swift Ltd.	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 0.05%w/vw+ Clobetasol Propionate BP 0.05%w/w cream	candidiasis & trichomonas infections. Certain types of fungal infections to skin. In psoriasis & eczematous dermatitis. Yeast infection and scaly patches.	i.TBD ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	J.B. Chemicals	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 0.05%w/vw+ Clobetasol Propionate BP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.02%w/w cream	It is indicated for treatment of skin associated with bacterial and fungal infection including contact dermatitis, seborrheic dermatitisan infective eczema.	i.Indication same as Annexure-A ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Blessing Healthcare	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 0.05%w/vw+ Clobetasol Propionate BP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.02%w/w cream	No	i.Indication mentioned in the package insert is dfiferent from the above.used for treatment, control, prevention and improvement of following conditions, diseases and symptoms: -Fungal infection -Skin infection -Bacterial infection -Redness, Itching, dryness and swelling of Scalp -.Redness, Itching, dryness and swelling of skin\-Psoriasis -Urinary tract infections –Respiratory infection –Soft tissue infection – Sexually transmitted infections –eye and ear infection –Protozoan infection -Infections during surgical procedures. ii. Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Macleods Pharmaceuticals	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 0.05%w/vw+ Clobetasol Propionate BP 0.05%w/w cream	Mixed skin infection and Vaginitis of bacterial and fungal origin	i.Indication same as Annexure-A ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Mascot Healthcare	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 1.0 %w/w+ Clobetasol Propionate BP 0.05%w/w cream	Resistant dermatoses such as recalcitrant eczemas and psoriasis (excluding widespread plaque psoriasis) where secondary bacterial or candida infection is present, suspected or likely to occur.	i.Indication same as Annexure-A ii.Marketed in Ukraine	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

5421

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Micro Laboratories	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 0.05%w/vw+ Clobetasol Propionate BP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.02%w/w cream	Administered topically on the surface of the skin for the management of polymicrobial skin infections.	i.Not Submitted ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Glenmark Pharmaceutical	Clobetasol Propionate BP 0.05 % w/w +Ofloxacin IP 0.75 % w/w +Ornidazole IP 2 % w/w +Terbinafine HCL BP 1 % w/w cream	Superficial skin infection of multimicrobialetiology associated with inflammation	i.Not Submitted ii.Not approved	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Anglo-French	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 1%w/vw+ Clobetasol Propionate BP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.02%w/w cream	Antibacterial, Steroid and antifungal combination for topical use	i. Peakge insert not submitted. ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Preet Remedies	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 1%w/vw+ Clobetasol Propionate BP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.02%w/w cream	Indications for individual components attached but not for the FDC.	i. Peakge insert not submitted. Ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Srishti Biotec	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 1%w/vw+ Clobetasol Propionate BP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.02%w/w cream	Indicaiton not mentioned.	i. Peakge insert not submitted. Ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Avni Pharma	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 0.1%w/vw+ Clobetasol Propionate BP 0.05%w/w + Chlorocresol IP 0.1%w/w (as preservative) cream	To be sold by retail on prescription of a registered medical practitioner.	I.Indication mentioned in package insert is different from above. Indications mentioned in package insert are; Dermatitis, Psoriasis, Lichen Planus ii.Marketed in India ,US	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Mepromax Lifesciences	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 1.0%w/vw+ Clobetasol Propionate BP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.02%w/w cream	Dermatitis, Skin Infection and Fungal Infection (as stated on the carton)	i.pcakage insert was not submitted ii.Not submitted.	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	HAB Pharmaceuticals	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl IP 1%w/vw+ Clobetasol Propionate IP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.20%w/w cream	Used for infection of the skin infection fungal infections inflammatory and pruritic manifestations of corticosteriod- responsive dermatomes, urinary tract infections skin infections and other conditions.	i.pcakage insert was not submitted ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Mepromax Lifesciences	Ofloxacin IP 0.75%w/w + Ornidazole IP 2.0%w/w + Terbinafine HCl BP 1.00%w/vw+ Clobetasol Propionate IP 0.05%w/w + Methylparaben (Preservative) 0.20%w/v + Propylparaben IP (Preservative) 0.02%w/w cream	Dermatitis, Skin Infection and Fungal Infection.	i.pcakage insert was not submitted ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Skymap Pharmaceutical	Clobetasol Propionate \ip 0.05%w/w+Ofloxacin IP 0.75%w/w+Ornidazole IP 2%w/w+Terbinafine HCl BP 1%w/w+Methyl Paraben IP 0.20%w/w (Preservative) + Propyl Paraben IP 0.02%w/w (Preservative) cream	Antifungal	i.pcakage insert was not submitted ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Skymap Pharmaceutical	Clobetasol Propionate \ip 0.05%w/w+Ofloxacin IP 0.75%w/w+Ornidazole IP 2%w/w+Terbinafine HCl BP 1%w/w+Methyl Paraben IP 0.20%w/w (Preservative) + Propyl Paraben IP 0.02%w/w (Preservative) cream	Antifungal	i.pcakage insert was not submitted ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Varav Biogenesis	Clobetasol Propionate USP 0.05%w/w+Ofloxacin IP 0.75%w/w +Ornidazole IP 2.00%w/w+Terbinafine HCl BP 1.00%w/w+Mehyl Paraben IP 0.20%w/w+Propyl Paraben IP 0.02%w/w (as preservative)	Antiinflamotory, antipruritic and vasoconstrictive.	i.Indication mentioned in package insert is different from above. Indications mentioned in package insert are: treatment of eczema, dermatitis, tinea infections, bacterial infections and scalp psoriasis. ii.not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Pharma Force	Clobetasol Propionate USP 0.05%w/w+Ofloxacin IP 0.75%w/w +Ornidazole IP 2.00%w/w+Terbinafine HCl BP 1.00%w/w+Mehyl Paraben IP 0.20%w/w+Propyl Paraben IP 0.02%w/w (as preservative)	Mixed infections of various etiology	i.Indication same as Annexure-A . ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Corona Remedies	Clobetasol Propionate IP 0.05%w/w+Ofloxacin IP 0.75%w/w +Ornidazole IP 2.00%w/w+Terbinafine HCl BP 1.00%w/w+Mehyl Paraben IP 0.20%w/w+Propyl Paraben IP 0.02%w/w (as preservative)	For treatment, control, prevention and improvement of following diseases, conditions and symptoms; Infections of Skin, Skin Infection, fungal infection, inflammatory and pruritic manifestations of corticosteroids-responsive dermatoses, Urinary tract infections, respiratory tract infections, kidneys infections, soft tissue infection, urethral and trichomonas infections.	i.pcakage insert was not submitted ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	Unimarck Pharma (I) Ltd	Each gm contains: Clobetasol propionate Ip 0.5mg Gentamicin sulphate IP eq. to Gentamicin 1.0mg Tolnaftate BP 10mg Iodochlorohydroxyquinoline IP 10mg Ketoconazole IP 20mg Cream base q.s.	Skin fungal infection	i.package insert was not submitted ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	I) Indication as per package insert ii) If marketing any where	
	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	DM Pharma	Clobetasol Propionate IP 0.05%w/w+Ofloxacin IP 0.75%w/w +Ornidazole IP 2.00%w/w+Terbinafine HCl BP 1.00%w/w+Mehyl Paraben IP 0.20%w/w+Propyl Paraben IP 0.02%w/w (as preservative)	Fungal Skin infections like athletes foor, ringorms etc.,	i. Used to treat bacterial and fungal infections, reduce inflammations and relief itch. It is used in corticosteroid responsive dermatomes complicated or threatened by secondary monomial and or bacterial infections ii. Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Terbinafine), high potency steroid (Clobetasol), anti-protozoal, anti-anaerobic, antibacterial (Ornidazole, Ofloxacin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
314	S.O. 1018 (E)	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1019(E)	Clobetasol +Neomycin +Miconazole +Zinc Sulphate	Ind-Swift Ltd.,	Clobetasol Propionate IP 0.05%w/w + Miconazole Nitrate IP 2.0%w/w + Neomycin Sulphaete IP eq. to Neomycin 0.5%w/w + Zinc Sulphate IP 2.0%w/w cream	It is used to treat severe inflammatory skin conditions such as eczema,dermatitis and psoriasis.	i.pcakage insert was not submitted ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Miconazole), high potency steroid (Clobetasol), anti-bacterial (Neomycin) & zinc sulphate in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. Although the company submitted a study data comparing steroid with steroid + zinc, there was no convincing evidence to support the combined use of the ingredients in this FDC. 4. No study is found supporting the combined use of ingredients in this FDC. 5. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1019(E)	Clobetasol +Neomycin +Miconazole +Zinc Sulphate	Varav Biogenesis	Clobetasol Propionate IP 0.05%w/w+Neomycin sulphate eq. to Neomycin IP 0.05%w/w+Miconazole Nitrate IP 2.0%w/w+Zinc Sulphate IP 2.0%w/w cream	Anti-inflammatory, Anti-Fungal, Anti-Bacterial and astringent	i.Indication same as Annexure-A . ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Miconazole), high potency steroid (Clobetasol), anti-bacterial (Neomycin) & zinc sulphate in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. Although the company submitted a study data comparing steroid with steroid + zinc, there was no convincing evidence to support the combined use of the ingredients in this FDC. 4. No study is found supporting the combined use of ingredients in this FDC. 5. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
315	S.O. 1019(E)	Clobetasol +Neomycin +Miconazole +Zinc Sulphate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1020(E)	Beclomethasone +Neomycin +Tolnaftate +Iodochlorhydroxyquinoline +Chlorocresol	Varav Biogenesis	Beclomethasone Dipropionat IP 0.025%w/w+Neomycin sulphate IP 0.50%w/w+Tolnaftate IP 2%w/w +Iodochlorhydroxyquinoline IP 2%w/w+Chlorocresol IP 0.1%w/w cream	Topical corticosteroid /anti bacterial/ anti fungal agent	i.Indication same as Annexure-A . ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Tolnaftate), high potency steroid (Beclomethasone Dipropionate), anti-bacterial (Iodochlorhydroxyquinolone, Neomycin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
316	S.O. 1020(E)	Beclomethasone +Neomycin +Tolnaftate +Iodochlorhydroxyquinoline +Chlorocresol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1021(E)	Betamethasone +Gentamycin +Zinc Sulphate +Clotrimazole +Chlorocresol	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Clotrimazole), steroid (Betamethasone), anti-bacterial (Gentamicin) & zinc sulphate in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
317	S.O. 1021(E)	Betamethasone +Gentamycin +Zinc Sulphate +Clotrimazole +Chlorocresol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & Justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 1022(E)	Borax + Boric acid + Naphazoline + Menthol + Camphor + methyl hydroxy benzoate	-	-	-	-	1. Pharmacodynamically inappropriate- Multiple ingredients (Menthol & Camphor) with unsubstantiated evidence of safety & benefit. There is no convincing scientific/ clinical evidence/ justification for the FDC.
315	S.O. 1022(E)	Borax + Boric acid + Naphazoline + Menthol + Camphor + methyl hydroxy benzoate	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification of this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

554

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1023(E)	Bromhexine + Dextromethorphan	-	-	-	-	1. Pharmacodynamically inappropriate: Dextromethorphan decreases the cough impulse so expulsion of secretion would be hampered whereas Bromhexine is mucolytic. 2. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
319	S.O. 1023(E)	Bromhexine + Dextromethorphan	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1024(E)	Dextromethorphan + Chlorpheniramine + Bromhexine	Puro Pharma	Dextromethorphan HCl IP 5mg+ Chlorpheniramine Maleate IP 2mg+ Bromhexine HCl IP 4mg per 5ml syrup	In the treatment of Dry cough	i) Same as Annexure A ii) No relevant data submitted.	1.Pharmacodynamically antagonistic and hence inappropriate Bromhexine is mucolytic, which liquifies mucus whereas Dextromethorphan is cough suppressant. Chlorpheniramine is also antihistaminic cough suppressant with anti-cholinergic property that dries up secretions. 2. Dextromethorphan and Chlorpheniramine, both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC as the combination can lead to excessive sedation. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
320	S.O. 1024(E)	Dextromethorphan + Chlorpheniramine + Bromhexine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
-	S.O. 1025(E)	Menthol + Anesthetic Ether	-	-	-	-	1. Pharmacodynamically irrelevant and indication is not clear. 2. No published literature supporting the use of this FDC.
321	S.O. 1025(E)	Menthol + Anesthetic Ether	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1026(E)	Dextromethorphan + Chlopheniramine + Ammonium Chloride + Sodium Citrate + Menthol	-	-	-	-	1. Pharmacodynamically antagonistic and hence inappropriate (Sodium citrate and Ammonium Chloride are expectorant whereas Chlorpheniramine dries up secretion and Dextromethorphan is cough supressant). 2. Dextromethorphan and Chlorpheniramine both cause sedation and drowsiness. It is inappropriate to combine these two drugs in FDC. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
222	**S.O. 1026(E)**	**Dextromethorphan + Chlopheniramine + Ammonium Chloride + Sodium Citrate + Menthol**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in (the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1027(E)	Ergotamine Tartrate+ Belladona dry extract + Caffeine + Paracetamol	Inga Laboratories	Ergotamine Tartrate IP 1mg+ Belladona dry extract IP 10mg+ Caffeine IP 100mg +Paracetamol IP 250mg tablet	Acute migraine, cluster headache	i)Acute attack of migraine with or without aura ii) Not provided	1. Paracetamol is an accepted analgesic for treatment of acute migraine attack, but the dose per tablet (250 mg) in this FDC is subtherapeutic. 2. Belladona extract contains the antimuscarinic agent atropine, but this is pharmacodynamically not relevant in acute migraine. Besides, being a plant extract, it would be liable to contain other uncharacterized ingredients. 3. Ergotamine carries risk of vascular problems if used frequently. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
323	S.O. 1027(E)	**Ergotamine Tartrate+ Belladona dry extract + Caffeine + Paracetamol**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1028 (E)	Phenytoin +Phenobarbitone sodium	Intas	Phenytoin sodium IP 100mg/100mg+Phenobarbitone IP 30mg/50mg uncoated tablet	For the control of generalized tonic-clonic (Grandmal) epilepsy and complex partial seizures.	i) same as Annexure A ii) Not submitted	The Subcommittee noted that this FDC is pre 1988. The Subcommittee observed that: 1. Both Phenytoin and Phenobarbitone have narrow therapeutic index and should not be combined as FDC as per guidelines. 2. As per IES guidelines, epilepsy treatment should always begin with monotherapy and if one drug is not effective, change to another drug. Treatment with two drugs can be considered only when monotherapy has not been effective. There too, FDC with two drugs with narrow margin of safety is irrational. 3. Availability of such combination will lead to misuse, with the patient being put on two drugs from the beginning without starting the patient on monotherapy. 4. The combination will lead to sedation which may impair day to day activities. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package Insert ii. Marketing anywhere	
	S.O. 1028 (E)	Phenytoin + Phenobarbitone sodium	Abbott Healthcare	Phenytoin Sodium IP 10mg+Phenobarbitone sodium IP 50mg	1. Partial seizures, whether or not they becomes secondarily generalized 2. Generalized epilepsy, if manifestating as tonic- clonic or tonic seizures or as myoclonic seizures (but only if beginning in adolescence or later life. The company at the time of Hearing submitted a package insert claimed to be revised on 18.01.2018 with indications as under: 1. Generalized epilepsy, if manifesting as tonic-clonic or tonic seizures, uncontrolled on monotherapy 2. Partial seizures, whether or not they become secondarily generalized uncontrolled on monotherapy.	i) same as Annexure A ii) Not submitted	The Subcommittee noted that this FDC is pre 1988. The Subcommittee observed that: 1. Both Phenytoin and Phenobarbitone have narrow therapeutic index and should not be combined as FDC as per guidelines. 2. As per IES guidelines, epilepsy treatment should always begin with monotherapy and if one drug is not effective, change to another drug. Treatment with two drugs can be considered only when monotherapy has not been effective. There too, FDC with two drugs with narrow margin of safety is irrational. 3. Availability of such combination will lead to misuse, with the patient being put on two drugs from the beginning without starting the patient on monotherapy. 4. The combination will lead to sedation which may impair day to day activities. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1028 (E)	Phenytoin +Phenobarbitone sodium	Intas Pharmaceuticals	Phenytoin Sodium IP 100mg/100mg+Phenobarbitone IP 30mg/50mg uncoated tablet	For the control of generalized tonic-clonic (grandmal and complex partial seizures)	i) same as Annexure A ii) Not submitted	The Subcommittee noted that this FDC is pre 1988. The Subcommittee observed that: 1. Both Phenytoin and Phenobarbitone have narrow therapeutic index and should not be combined as FDC as per guidelines. 2. As per IES guidelines, epilepsy treatment should always begin with monotherapy and if one drug is not effective, change to another drug. Treatment with two drugs can be considered only when monotherapy has not been effective. There too, FDC with two drugs with narrow margin of safety is irrational. 3. Availability of such combination will lead to misuse, with the patient being put on two drugs from the beginning without starting the patient on monotherapy. 4. The combination will lead to sedation which may impair day to day activities. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1028 (E)	Phenytoin + Phenobarbitone sodium	Anglo-French	Phenytoin Sodium IP 100mg+Phenobarbitone IP 30mg uncoated tablet	Grandmal epilepsy, Partial seizures, Simple partial, Complex partial	i) Not submitted ii) Not submitted	The Subcommittee noted that this FDC is pre 1988. The Subcommittee observed that: 1. Both Phenytoin and Phenobarbitone have narrow therapeutic index and should not be combined as FDC as per guidelines. 2. As per IES guidelines, epilepsy treatment should always begin with monotherapy and if one drug is not effective, change to another drug. Treatment with two drugs can be considered only when monotherapy has not been effective. There too, FDC with two drugs with narrow margin of safety is irrational. 3. Availability of such combination will lead to misuse, with the patient being put on two drugs from the beginning without starting the patient on monotherapy. 4. The combination will lead to sedation which may impair day to day activities. There is no sound scientific/ clinical evidence/ justification for the FDC.
324	S.O. 1028 (E)	Phenytoin + Phenobarbitone sodium	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1029(E)	Gliclazide 40mg+ Metformin 400mg	-	-	-	-	1. Dosage of Metformin is sub-therapeutic. 2. The increments in dose of Metformin are made in steps of 500mg as per treatment guidelines. 3. Ratio of Gliclazide and Metformin is not appropriate for rational dose adjustment. There is no sound scientific/ clinical evidence/ justification for the FDC.
325	S.O. 1029(E)	Gliclazide 40mg+ Metformin 400mg	The Subcommittee is of the opinion that: There is no therapeutic justification for the quantity of ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1030(E)	Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine	Ipca	Paracetamol IP 125mg+ Ambroxol HCl IP 7.5mg+ Phenylephrine HCl IP 2.5mg+ Chlorpheniramine Maleate IP 1mg per ml drops	Symptomatic relief of cold, cough and fever associated with respiratory tract infections.	i) There is a mismatch between indications mentioned in Annexure A and indications mentioned in the package insert: Symptomatic relief of cough is not mentioned in the package insert. ii) Not Available	1.Pharmacodynamically antagonistic and hence inappropriate Ambroxol is mucolytic, which liquifies mucus whereas Chlorpheniramine is an antihistaminic cough suppressnat with anti-cholinergic property that dries up secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1030(E)	Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine	Indoco Remedies	Paracetamol IP 125mg+ Ambroxol HCl IP 7.5mg+ Phenylephrine HCl IP 2.5mg+ Chlorpheniramine Maleate IP 1mg per 5ml drops	Common cold, associated with productive cough, fever, headache and bodyache.	i) Indication mentioned do not match with above- Productive cough, fever and headache are not mentioned in package insert. ii) Not Approved	1.Pharmacodynamically antagonistic and hence inappropriate Ambroxol is mucolytic, which liquifies mucus whereas Chlorpheniramine is an antihistaminic cough suppressnat with anti-cholinergic property that dries up secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1030(E)	Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine	Ipca	Paracetamol IP 125mg+ Ambroxol HCl IP 15mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine Maleate IP 2mg per 5ml syrup	Symptomatic relief of cold, cough and fever associated with respiratory tract infections.	i) There is a mismatch between indications mentioned in Annexure A and indications mentioned in the package insert: Symptomatic relief of cough is not mentioned in the package insert. ii) Not Available	1.Pharmacodynamically antagonistic and hence inappropriate Ambroxol is mucolytic, which liquifies mucus whereas Chlorpheniramine is an antihistaminic cough suppressnat with anti-cholinergic property that dries up secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1030(E)	Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine	Indoco Remedies	Paracetamol IP 125mg+ Ambroxol HCl IP 15mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine Maleate IP 2mg per 5ml syrup	Common cold, associated with productive cough, fever, headache and body ache.	i) here is a mismatch between indications mentioned in Annexure A and indications mentioned in the package insert: Productive cough, fever and headache are not mentioned in package insert. ii) Not Approved	1.Pharmacodynamically antagonistic and hence inappropriate Ambroxol is mucolytic, which liquifies mucus whereas Chlorpheniramine is an antihistaminic cough suppressnat with anti-cholinergic property that dries up secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1030(E)	Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine	Ipca	Paracetamol IP 250mg+ Ambroxol HCl IP 15mg+ Phenylephrine HCl IP 5mg+ Chlorpheniramine Maleate IP 2mg per 5ml syrup	Symptomatic relief of cold, cough and fever associated with respiratory tract infections.	i) here is a mismatch between indications mentioned in Annexure A and indications mentioned in the package insert: Symptomatic relief of cough is not mentioned in the package insert ii) Not Available	1.Pharmacodynamically antagonistic and hence inappropriate Ambroxol is mucolytic, which liquifies mucus whereas Chlorpheniramine is an antihistaminic cough suppressnat with anti-cholinergic property that dries up secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1030(E)	Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine	Skymap Pharmaceutical	Paracetamol IP 125mg + Ambroxol HCl IP7.5mg + Phenylephrine HCl IP 2.5mg + Chlorpheniramine Maleate IP 1mg per ml drops	Anti cough	i) Not submitted ii) Not Available	1.Pharmacodynamically antagonistic and hence inappropriate Ambroxol is mucolytic, which liquifies mucus whereas Chlorpheniramine is an antihistaminic cough suppressnat with anti-cholinergic property that dries up secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
326	S.O. 1030(E)	Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Mankind	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml oral suspension	Diarrhoea of mixed infection in children.	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Macleods	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml oral suspension	Indicated for the treatment of Diarrhoea and dysentery.	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Aristo	Ofloxacin 125mg+ Ornidazole IP 50mg per 5ml oral suspension	1. Treatment is suspected or confirmed polymicrobial infections caused by susceptible anaerobic and aerobic organisms, e.g. chronic sinusitis, lung abscess, emphyma, intra-abdominal infections, chronic osteomyelitis, skin and soft tissue infections in devitalized tissues and oro-dental infections. 2. Treatment of diarrhoea and dysentery of amoebic or mixed amoebic and bacterial origin.	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Micro	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml oral suspension	Indicated for mixed gastrointestinal infections.	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Akums Drugs	Ofloxacin IP 50mg + Ornidazole IP 125mg per 5ml suspension	Treatment of diarrhoea of mixed infection.	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Laborate Pharmaceutical	Ofloxacin IP 50mg + Ornidazole IP 125mg per 5ml suspension	Amoebiasis, bacterial infections.	i) Ofloxacin is a synthetic 4-fluoroquinolone antibacterial agent with bactericidal activity against a wide range of gram negative and gram positive organisms. It is indicated for the treatment of following infections when caused by sensitive organisms.Upper and lower urinary tract infections ,uncomplicated urethral and cervical gonorrhoea, non gonococcal urethritis and cervicitis,skin and soft tissue infections. Ornidazole is used in the following conditions: Anaerobic infections both pre and post operatively, bacterial Vaginosis,amoebic dysentery,amoebic liver abscess,hepatic and intestinal amoebiasis. ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Ind-Swift Ltd.,	Ofloxacin IP 50mg + Ornidazole IP 125mg per 5ml suspension	To cure mild to moderate infections due to susceptible strains of designated micro organisms, to treat certain prostate infections and STIs, trichomoniasis of uro-genital tract and bacterial vaginosis, used in treatment and prophylaxis of susceptible anaerobic infections in dental and gastro intestinal surgery	i) Not submitted ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.

569

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Ozone Pharmaceuticals	Ofloxacin IP 50mg + Ornidazole IP 125mg per 5ml suspension	Ofloxacin +Ornidazole, a combined formulation of antibiotics, is prescribed for the treatment of peridonitis, diarrhoea, dysentery, gingivitis and pelvic inflammatory disease, urinary tract infections, respiratory infections, soft tissue infections, Typhoid fever.	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Emcure Pharmaceuticals	Ofloxacin IP 50mg + Ornidazole IP 125mg per 5ml suspension	For the treatment of diarrhoea of mixed infection.	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Mascot Healthcare	Ofloxacin IP 50mg + Ornidazole IP 125mg per 5ml suspension	To treat Fungal Infections, infections in Digestive Tract, respiratory Infections	i) Indications for Ornidazole :Amoebiasis, Giardiasis, trichomonas Vaginitis, Anaerobic bacterial infections, Bacterial Vaginitis Indications for Ofloxacin: Bronchitis, Pneumonia, Urinary Tract Infections, Bone and Joint Infections, Gonorrhoea, ENT Infectins, Skin and soft tissue infections, Typhoid Fever, Prostatis, Otitis, Gynaecological Infections, Conjunctivitis, Keratitis, Urethritis, Cervicitis ii) Not provided	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Group Pharmaceuticals	Oflaxacin + Ornidazole suspension	Not submitted	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Mendine Pharmaceuticals	Ofloxacin USP 50mg+ Ornidazole IP 125mg SUSPENSION	For treatment of Infantile Colitis, diarrhea of mixed infection and in dysentry	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Puro Pharma	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml suspension	For treatment of common cold and Allergic rhinitis	i) Indication as per Package insert: Bacterial infections such as Diarrhoea, dysentery, Pelvic Inflammatory disease, Post surgical care, Dental Infections, Urinary Tract Infections, ENT infections, Skin and soft tissue infections ii) Approved in Germany, Thailand, Ukraine and France	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	PharmaSynth	Ofloxacin IP 50mg+ Ornidazole IP 125mg er 5ml suspension	Anti-diarrhoeal	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Chemonix India	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml suspension	Abdominal pain and antidiarrhoeal	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Jenburkt Pharmaceuticals	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml suspension	Acute diarrhea of mixed aetiology	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Three B Health Care	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml suspension	Amoebiasis, Bacterial infections.	i) Bacterial vaginosis, amoebic dysentery,amoebic liver abscess, hepatic and intestinal amoebiasis ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Skymap Pharmaceutical	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml suspension	Anti bacterial	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Skymap Pharmaceutical	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml suspension	Anti bacterial	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Pharma Force	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml suspension	Diarrhoea and Mixed infection	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Copmed Pharmaceuticals	Ofloxacin IP 50mg + Ornidazole IP 125mg per 5ml suspension	Diarrhoea of mixed infection	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Celsius Healthcare	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml suspension	For treatment of Diarrhoea	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Synchem Laboratories	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml suspension	Diarrhoea and Dysentery	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	DM Pharma	Ofloxacin IP 50mg+ Ornidazole IP 125mg per 5ml syrup	Giardisis, trichomoniais, amoebiasis, amoebic dysentery. (as submitted)	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Meridian Medicare	Ofloxacin IP 50mg+ Ornidazole IP 125mg suspension	Diarrohea and Dysentery.	i) same as Annexure A ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea casued by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	Creative Healthcare	Each 5ml suspension contains: Ofloxacin IP 50mg+ Ornidazole IP 125mg	Not submitted	i) Not submitted ii) Not submitted	1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. Diarrhoea of mixed infection in children is uncommon and epidemiological data could not be provided by the appellant. 2. It is not possible to differentiate clinically between diarrhoea caused by single agent or by multiple organisms. Hence, the FDC will be used indiscriminately resulting in emergence of resistance to Ofloxacin. Fluoroquinolones have been classified by WHO under "Watch" category of antimicrobials which have higher resistance potential and are recommended as first or second choice of treatments only for a specific, limited number of indications. 3. Safety concerns in paediatric patients for Ofloxacin. 4. This combination is not as per standard therapeutic guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
327	S.O. 1031(E)	Ofloxacin + Ornidazole suspension	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1032	Albuterol + Etofylline + Bromhexine + Menthol	-	-	-	-	1. As per guidelines there is no role of mucolytics (Bromhexine) in ashthma. 2. Use of mucolytic alongwith anti-asthmatic drug is liable to be misused as expectorant, exposing the patients unnecessarily to the anti-asthamatic drug (albuterol) and its adverse effects. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
328	S.O. 1032	**Albuterol + Etofylline + Bromhexine + Menthol**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1033(E)	Albuterol + Bromhexine + Theophylline	Systopic Laboratories	Albuterol Sulphate IP eq. to Albuterol 4mg+ Bromhexine HCl IP 8mg+ Theophylline (Anhydrous) IP 200mg uncoated tablet	As an anti Bronchodilator	i) Indication for FDC is not properly given. ii) Not Available	1. Theopylline has a narrow therapeutic index and hence as per guidelines not suitable for combining in FDC. 2. There is no therapeutic justification for the ingredients to be combined. 3. This FDC is not as per standard therapeutic guidelines 4. Indication mentioned by the appelant also does not specify the population that may benefit. There is no sound scientific/ clinical evidence/ justification for the FDC. During the hearing given to the appellant, it was commented that the manufacturing of this FDC has been stopped by the appellant.
329	S.O. 1033(E)	Albuterol + Bromhexine + Theophylline	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1034(E)	Salbutamol + Hydroxyethyltheophylline (Etofylline)+ Bromhexine	Centaur	Salbutamol sulphate IP eq. To Salbutamol 2mg+ Etofylline IP 200mg+ Bromhexine HCl IP 8mg uncoated tablet	For relief of bronchospasm in adults and children 6 years of age and older with reversible obstructive airway disease due to asthma, chronic bronchitis or COPD.	i) Same as Annexure A ii) Not Available	During hearing, the appellant claimed that this FDC is pre 1988. However, the appellant could not produce any documentary evidence. The Subcommittee noted that: 1. This combination is not as per the standard treatment guidelines for Asthma or COPD. 2. There is no therapeutic justification for ingredients to be combined: Mucolytic (Bromhexine) is not indiacted in bronchial asthma. 3. Mucolytic (Bromhexine) along with anti-asthmatic drugs is likely to be misused as an expectorant by the patients having cough, exposing them unnecessarily to the antiasthmatic drugs and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1034(E)	Salbutamol + Hydroxyethyltheophylline (Etofylline)+ Bromhexine	Centaur	Salbutamol sulphate IP eq. To Salbutamol 1mg+ Etofylline IP 50mg+ Bromhexine HCl IP 4mg per 5ml syrup	For relief of bronchospasm in adults and children 6 years of age and older with reversible obstructive airway disease due to asthma, chronic bronchitis or COPD.	i) Same as Annexure A ii) No relevant data submitted.	During hearing, the appellant claimed that this FDC is pre 1988. However, the appellant could not produce any documentary evidence. The Subcommittee noted that: 1. This combination is not as per the standard treatment guidelines for Asthma or COPD. 2. There is no therapeutic justification for ingredients to be combined: Mucolytic (Bromhexine) is not indiacted in bronchial asthma. 3. Mucolytic (Bromhexine) along with anti-asthmatic drugs is likely to be misused as an expectorant by the patients having cough, exposing them unnecessarily to the antiasthmatic drugs and their side effects. There is no sound scientific/ clinical evidence/ justification for the FDC.
330	S.O. 1034(E)	Salbutamol + Hydroxyethyltheophylline (Etofylline)+ Bromhexine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1035(E)	Paracetamol + Phenylephrine + Levocetirizine + Sodium Citrate	Centaur	Paracetamol IP 250mg+ Phenylephrine HCl IP 5mg+ Levocetirizine HCl IP 1.25mg + Sodium Citrate IP 60mg per 5ml suspension	Common cold and allergic rhinitis.	i) Same as Annexure A ii) Not available	1. Sodium citrate is not indicated in common cold and allergic rhinitis 2. Pharmacokinetic incompatibility: Paracetamol is given 4 times a day. Levocetirizine once a day. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 5. This combination is not as per the standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
331	S.O. 1035(E)	**Paracetamol + Phenylephrine + Levocetirizine + Sodium Citrate**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1036(E)	Paracetamol+ Propyphenazone+ Caffeine	Ajanta	Paracetamol IP 250mg+ Propyphenazone IP 150mg+ Caffeine (Anhydrous) IP 30mg uncoated tablet	Indicated for the relief of headache, migraine, toothache, menstrual pain, post operative pain rheumatology and pain fever associated with and flu.	i)Relief of headache toothache, menstrual pain post-operative pain, rheumatology and pain and fever associated with flu ii) i) Marketed :Spain, Netherlands, Latvia and Philippines ii) Approved :Spain, Netherlands, Latvia and Philippines iii) Approved as IND : Not submitted iv) withdrawn, if any, with reasons :Italy(ITA): Having regard to the adverse effects associated with their long term use, products containing propyphenazone may now be indicated only for the short term treatment of severe pain or pyrexia	1. Propyphenazone has risk of adverse reactions like skin rashes, pruritus, erythema, asthma precipitation, angioedema, and anaphylaxis, thrombocytopenia, leukopenia, agranulocytosis, and pancytopenia. Although uncommon these reactions can be severe and potentially fatal. This has led to withdrawal of propyphenazone containing preparations in some countries. 2. The appellant emphasized on one published paper which provided pooled statistical analysis of previously completed single dose, single blind (7 studies) and double blind (1 study), parallel, randomised studies in dental pain comparing this FDC with Paracetamol and *placebo*. The author concluded that the pooled analysis should be confirmed in a double blind study since seven studies included in this paper were single blinded. 3. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification submitted for this FDC for the indications mentioned.
	S.O. 1036(E)	Paracetamol+ Propyphenazone+ Caffeine	Juggat	Paracetamol IP 300mg+Propyphenazone IP 150mg+Caffeine (anhydrous) IP 50mg uncoated tablet	It is used in the treatment of Headache , musculoskeletal pain , migraine.and tooth ache.	i) Not submitted ii)i) Marketed :India, Italy & Spain ii) Approved :India, Italy & Spain	1. Propyphenazone has risk of adverse reactions like skin rashes, pruritus, erythema, asthma precipitation, angioedema, and anaphylaxis, thrombocytopenia, leukopenia, agranulocytosis, and pancytopenia. Although uncommon these reactions can be severe and potentially fatal. This has led to withdrawal of propyphenazone containing preparations in some countries. 2. The appellant emphasized on one published paper which provided pooled statistical analysis of previously completed single dose, single blind (7 studies) and double blind (1 study), parallel, randomised studies in dental pain comparing this FDC with Paracetamol and *placebo*. The author concluded that the pooled analysis should be confirmed in a double blind study since seven studies included in this paper were single blinded. 3. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification submitted for this FDC for the indications mentioned.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1036(E)	Paracetamol+ Propyphenazone+ Caffeine	Piramal Enterprises	Paracetamol IP 250.0mg+ Propyphenazone IP 150.0mg+ Caffeine IP (anhydrous) 50.0mg uncoated tablet	Analgesic	i) Not submitted ii) i) Marketed : Brazil, Indonesia, Philippines, Kuwait etc.	1. Propyphenazone has risk of adverse reactions like skin rashes, pruritus, erythema, asthma precipitation, angioedema, and anaphylaxis, thrombocytopenia, leukopenia, agranulocytosis, and pancytopenia. Although uncommon these reactions can be severe and potentially fatal. This has led to withdrawal of propyphenazone containing preparations in some countries. 2. The appellant emphasized on one published paper which provided pooled statistical analysis of previously completed single dose, single blind (7 studies) and double blind (1 study), parallel, randomised studies in dental pain comparing this FDC with Paracetamol and *placebo*. The author concluded that the pooled analysis should be confirmed in a double blind study since seven studies included in this paper were single blinded. 3. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification submitted for this FDC for the indications mentioned.
332	S.O. 1036(E)	Paracetamol+ Propyphenazone+ Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1037 (E)	Guaifenesin+ Diphenhydramine+ Bromhexine+ Phenylephrine	-	-	-	-	1.Pharmacodynamically antagonistic and hence inappropriate: Diphenhydramine is an anti-histaminic cough sppressant and anti-cholinergic agent that dries up secretion while Guaiphenesin is expectorant and bromhexine is mucolytic. 2. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. The combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
333	S.O. 1037 (E)	Guaifenesin+ Diphenhydramine+ Bromhexine+ Phenylephrine	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

me

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O. 1038(E)	Dried Alumnium Hydroxide Gel + Propantheline Bromide + Diazepam	-	-	-	-	1. No published literature supporting the FDC. 2. In present scenario Propanthaline has safety concerns. 3. Use of diazepam in this FDC is irrational. 4. This combination is not as per standard therapeutic guidelines. There is no convincing scientific/ clinical evidence/ justification for the FDC.
334	S.O. 1038(E)	Dried Alumnium Hydroxide Gel + Propantheline Bromide + Diazepam	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940 In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1039(E)	Bromhexine + Phenylephrine + Chlorpheniramine + Paracetamol	NuLife	Paracetamol IP 125mg+ Bromhexine HCl IP 4mg+ Phenylephrine HCl IP 2.5mg+ Chlorpheniramine Maleate IP 1mg per 5ml syrup	Common cold and cough associated with fever	i) Package insert indication does not match with above- Adjunct with anti bacterials in sinusitis, tonsillitis and otitis media is mentioned in the package insert.Relief of nasal and sinus congestion,relief of symptoms of nose or throat due to upper respiratory tract allergies, relief of sinus pain and headache. ii) Not Available	1. There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Bromhexine is a mucolytic agent and increases secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per the standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
	S.O. 1039(E)	Bromhexine + Phenylephrine + Chlorpheniramine + Paracetamol	Navil Laboratories	Bromhexine HCl IP 4mg+ Phenylephrine HCl IP 2.5mg+ Chlorpheniramine Maleate IP 1.25mg+ Paracetamol IP 125mg per 5ml syrup	In the treatment of upper respiratory tract infections associated with cough, cough, cold and fever in children.	i) Same as Annexure A ii) Not submitted relevant status.	1. There is pharmacodynamic antagonism and hence inappropriate: Chlorpheniramine is anti-histaminic cough suppressant with anti-cholinergic property that dries up secretions whereas Bromhexine is a mucolytic agent and increases secretions. 2. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 3. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 4. This combination is not as per the standard treatment guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
335	S.O. 1039(E)	Bromhexine + Phenylephrine + Chlorpheniramine + Paracetamol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

me

335

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1040(E)	Beclomethasone +Clotrimazole+Gentamicin+IodoChlorhydroxyquinoline	-	-	-	-	1. Pharmacodynamically inappropriate- Each ingredient of the FDC has different therapeutic indication. There is no therapeutic justification for combining antifungal (Clotrimazole), steroid (Beclomethasone Dipropionate), anti-bacterial (Iodochlorhydroxyquinolone, Gentamicin) in this FDC. 2. The FDC is likely to cause emergence of both bacterial and fungal resistance and adverse effects of potent steroid. 3. No study is found supporting the combined use of ingredients in this FDC. 4. This combination is not as per standard therapeutic guidelines/ standard text books. There is no sound scientific/ clinical evidence/ justification for the FDC.
336	S.O. 1040(E)	Beclomethasone +Clotrimazole+Gentamicin+IodoChlorhydroxyquinoline	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure - A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 1041(E)	Telmisartan + Metformin	-	-	-	-	1. There is no rationale of combining Metformin (oral hypoglycaemic agent) and Telmisartan (anti-hypertensive) in an FDC. 2. These two drugs are used in patients with coexisting diabetes and hypertension. However, dose adjustment of individual drugs will be needed. This will not be possible with this FDC leading to overdosing or underdosing which may precipitate risk to the patients. There is no scientific/ clinical evidence/ justification for the FDC.
337	S.O. 1041(E)	Telmisartan + Metformin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

one

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 1042(E)	Ammonium Citrate + Vitamin B 12+ Folic Acid + Zinc Sulphate	-	-	-	-	1. Pharmacodynamically irrelevant 2. Therapeutic area and quantity of ingredients not clear 3. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
338	S.O. 1042(E)	Ammonium Citrate + Vitamin B 12+ Folic Acid + Zinc Sulphate	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1043(E)	Levothyroxine pyridoxine+ Nicotinamide	-	-	-	-	1. Levothyroxine has narrow therapeutic index. 2. Hence, as per guidelines, it cannot be combined in an FDC. 3. There is no rationale for this FDC and this combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
339	S.O. 1043(E)	Levothyroxine pyridoxine+ Nicotinamide	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1044(E)	Benfotiamine+ Metformin	-	-	-	-	The Subcommittee noted that this FDC was discussed by previous "10 expert Committee" on 27.08.14 as under- "The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC." The Subcommittee concurred with above. Also: 1. There is no published literature supporting the superior efficacy of combination of two drugs. 2. Use of Benfotiamine as prophylaxis/treatment is not documented. 3. This combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
340	S.O. 1044(E)	Benfotiamine+ Metformin	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1045(E)	Thyroid +Thiamine + Riboflavin + Pyridoxine + Calcium Pantothenate + Tocopheryl Acetate + Nicotinamide	-	-	-	-	1. Thyroxine has narrow therapeutic index. 2. Hence, as per guidelines, it cannot be combined in an FDC. 3. There is no rationale for this FDC and this combination is not as per standard therapeutic guidelines. There is no sound scientific/ clinical evidence/ justification for the FDC.
34)	S.O. 1045(E)	Thyroid +Thiamine + Riboflavin + Pyridoxine + Calcium Pantothenate + Tocopheryl Acetate + Nicotinamide	The Subcommittee is of the opinion that: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure A (Provided By company)	i. Indicaiton as per package insert ii. If marketing any where	
	S.O. 1046(E)	Ascorbic Acid + Menadione Sodium Bisulphate + Rutin + Dibasic Calcium Phosphate + Adrenochrome Mono Semicarbazone	-	-	-	-	1. Such combinations have been used as non specific haemostatic agents. 2. In the present FDC, the quantity of various ingredients is not known. 3. There is no sound scientific /clinical evidence to use this FDC as haemostatic agents. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
342	S.O. 1046(E)	Ascorbic Acid + Menadione Sodium Bisulphate + Rutin + Dibasic Calcium Phosphate + Adrenochrome Mono Semicarbazone	Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1047	Phenylephrine+ Chlorpheniramine+ Paracetamol+ Bromhexine+ Caffeine	NuLife	Phenylephrine HCl IP 5mg + Chlorpheniramine Maleate IP 2mg+ Paracetamol IP 325mg+ Bromhexine HCl IP 8mg+ Caffeine Anhydrous IP 15mg uncoated tablet	Common cold and cough associated with fever	Indication mentioned in package insert does not match with Annexure A. Additional indications mentioned in package insert are: Nasal and sinus congestion, Allergic symptoms of nose or throat due to upper respiratory tract allergy, relief from sinus pain and headache.Adjunct with anti bacterial actions in sinusitis, tonsillitis and otitis media.	1. Pharmacodynamically antagonistic and hence inappropriate: Chlorpheniramine is an anti-histaminic cough suppressant with anti-cholinergic properties that dries up secretion while bromhexine is mucolytic which make mucus more fluidy. 2. There is no rationale in combining five ingredients in single FDC as patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of orally administered Phenylephrine as a nasal decongestant. 4. Caffeine content in this formulation is not adequate to justify "analgesia adjuvant" effect. 5.This combination is not as per standerd treatment guidelines There is no sound scientific/ clinical evidence/ justification for the FDC.
343	S.O. 1047	Phenylephrine+ Chlorpheniramine+ Paracetamol+ Bromhexine+ Caffeine	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1048(E)	Clotrimazole +Beclomethasone +Lignocaine +Ofloxacin +Acetic Acid + Sodium Methyl Paraben +Propyl Paraben	NuLife	Clotrimazole IP 1.0%w/v+Beclomethasone Dipropionate IP 0.025%w/v+Ofloxacin IP 0.3%w/v+Lignocaine HCl IP 2.0%w/v+Acetic Acid IP 2.0%w/v+Antioxidant - BHA BP 0.1%w/v+Sodium Methyl Paraben IP 0.1%w/v+Propyl Paraben IP 0.02%w/v ear drops	For Fungal and Bacterial infection in Otitis Externa associated with Eczematous Inflammation Otomycosis, Chronic Suppurative Otitis Media	i.Indication same as Annexure-A ; ii.Not submitted	1. Pharmacodynamically inappropriate- Each ingredient of FDC has different therapeutic indication. 2. Combining antibacterial (Ofloxacin) , antifungal (Clotrimazole), steroid (Beclomethasone) in the present FDC is liable to be misused. Patients may not need all the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredients and their side effects. 3. There is no reasonable evidence of efficacy of Lignocaine as a local anaesthetic when applied over skin (external ear canal). 4. Publications regarding etiopathology of otitis externa/ otitis media, spectrum of anti-fungal and anti-bacterial action of ingredients of this FDC & Clinical Trials reported did not justify this FDC. There is no sound scientific/ clinical evidence/ justification for the FDC.
344	S.O. 1048(E)	Clotrimazole +Beclomethasone +Lignocaine +Ofloxacin +Acetic Acid + Sodium Methyl Paraben +Propyl Paraben	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1851(E)	Fixed Dose Combinations Of Nimesulide + Levocetrizine	-	-	-	-	The Subcommittee noted that FDC of Nimesulide 100mg ER + Levocetirizine HCl 5mg Tablets indicated for symptomatic treatment of acute rhinosinusitis is approved by CDSCO on 28.03.08. The Subcommittee further noted that FDC Nimesulide + Levocetirizine was also deliberated by SEC (Pulmonary) in its meeting held on 24.09.2014: "The SEC committee examined and opined that the FDC is not rational as levocetirizine is anti-histaminic whereas Nimesulide is an antipyretic analgesic and the combination is likely to be misused/overused in situations where single drug is required. Further this FDC is not approved anywhere in the world. Hence the SEC committee did not recommend for its continued marketing in the country." The DTAB Subcommittee concured with the opinion of SEC and further noted that: 1. There is Pharmacokinetic mismatch between Nimesulide (given twice a day) and Levocetirizine (given once a day). 2. Use of Nimesulide is banned below the age of 12 years due to potential hepatotoxicity. There is no sound scientific/ clinical evidence/ justification for the FDC.
345	**S.O. 1851(E)**	**Fixed Dose Combinations Of Nimesulide + Levocetrizine**	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O.1852(E)	Ofloxacin + Ornidazole injection	Crest Lifesciences	Ofloxacin IP 50mg+ Ornidazole IP 125mg injection	Ofloxacin- treatment of patients to cure mild to moderate infection due to susceptible strains of designated microorganisms., it is used to treat certain prostate infections and sexually transmitted infections. Ornidazole- Trichomoniasis of uro-gential tract and bacterial vaginosis.Ornidazole suspension is used in the treatment and prophylaxis of susceptible anaerobic infections in dental and gastrointestinal surgery.	i) Not submitted ii) Not submitted	1.The Subcommittee noted that FDC of Ofloxacin 2mg + Ornidazole 5 mg per ml Infusion was approved by DCGI on 17.8.2009 for the treatment of diarrhoea of mixed infection in adult patients. 2. The FDC of Ofloxacin + Ornidazole injection was deliberated upon by NDAC (Antimicrobial, Antiparasitic, Antifungal & Antiviral) in its meeting held on 28.02.2014 . The Committee noted the recommendation of the Parliament Standing Committee (PSC) and evaluated this drug in present scenario. The firm presented the data of a phase III trial. The committee noted that parenteral use of antibacterial in acute diarrhoea is not recommended routinely. There is no specific advantage of giving Fluroquinolone and imidazole in parental form as both can be given individually, if indicated. The FDC will not be rationale. Hence, the committee did not recommend the FDC for continued marketing in India for the present approved indication of diarrhoea. The Subcommittee concurred with above comments from NDAC committee and noted that: 1. Both the ingredients have different therapeutic indications. The indications mentioned by the company are too broad. 2. This combination is not mentioned in standard treatment guideline for the indications mentioned. 3. The FDC may involve unnecessary exposure to two anti-microbial agents where one is adequate increasing the risk of developing anti microbial resistance and also increasing the risk of side effects to human beings. There is no sound scientific/ clinical evidence/ justification for the FDC for the indications mentioned.
	S.O.1852(E)	Ofloxacin + Ornidazole injection	Akums Drugs	Ofloxacin IP 100mg+Ornidazole IP 500mg per 100ml injection	For treatment of Diarrhoea of mixed infection in adult patients only	i) Not submitted ii) Not approved	1. The Subcommittee noted that FDC of Ofloxacin 2mg + Ornidazole 5 mg per ml Infusion was approved by DCGI on 17.8.2009 for the treatment of diarrhoea of mixed infection in adult patients. 2. The FDC of Ofloxacin + Ornidazole injection was deliberated by NDAC (Antimicrobial, Antiparasitic, Antifungal & Antiviral) in its meeting held on 28.02.2014 . The Committee noted the recommendation of the Parliament Standing Committee (PSC) and evaluated this drug in present scenario. The firm presented the data of phase III trial data. The committee noted that parenteral use of antibacterial in acute diarrhoea is not recommended routinely. There is no specific advantage of giving Fluroquinolone and imidazole in parental form as both can be given individually, if indicated. The FDC will not be rationale. Hence, the committee did not recommend the FDC for continued marketing in India for the present approved indication of diarrhoea. The Subcommittee concurred with above comments from NDAC committee and noted that: 1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. 2. Ornidazole is effective against infective diarrhoea due to protozoal infection and this may encourage its indiscriminate use, particularly when combined with a fluoroquinolone like ofloxacin. This will enhance emergence of antimicrobial resistance against quinolones. 3. Safety concerns regarding misuse of this FDC containing Ofloxacin in paediatric patients. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O.1852(E)	Ofloxacin + Ornidazole injection	Ahlcon Parenterals	Ofloxacin IP 200mg+ Ornidazole IP 500mg infusion	For Acute Diarrhoea and Dysentery in adults	i) same as Annexure A ii) Not submitted	1. The Subcommittee noted that FDC of Ofloxacin 2mg + Ornidazole 5 mg per ml Infusion was approved by DCGI on 17.8.2009 for the treatment of diarrhoea of mixed infection in adult patients. 2. The FDC of Ofloxacin + Ornidazole injection was deliberated by NDAC (Antimicrobial, Antiparasitic, Antifungal & Antiviral) in its meeting held on 28.02.2014 . The Committee noted the recommendation of the Parliament Standing Committee (PSC) and evaluated this drug in present scenario. The firm presented the data of phase III trial data. The committee noted that parenteral use of antibacterial in acute diarrhoea is not recommended routinely. There is no specific advantage of giving Fluroquinolone and imidazole in parental form as both can be given individually, if indicated. The FDC will not be rationale. Hence, the committee did not recommend the FDC for continued marketing in India for the present approved indication of diarrhoea. The Subcommittee concurred with above comments from NDAC committee and noted that: 1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. 2. Ornidazole is effective against infective diarrhoea due to protozoal infection and this may encourage its indiscriminate use, particularly when combined with a fluoroquinolone like ofloxacin. This will enhance emergence of antimicrobial resistance against quinolones. 3. Safety concerns regarding misuse of this FDC containing Ofloxacin in paediatric patients. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O.1852(E)	Ofloxacin + Ornidazole injection	Venus Remedies	Ofloxacin IP 200mg+ Ornidazole IP 500mg infusion	Major Indications • Prophylactical intraabdominal surgery and post surgical infection caused by anaerobic bacteria. • Intra-abdominal infections of bacterial and/or protozoal origin (amoebiasis / giardiasis, severe intestinal amoebiasis, all extra – intestinal amoebiasis forms, giardiasis, liverabscess and appendicitis. • Complicated urogenital infections including pelvic infections, trichomoniasis, bacterial vaginosis and other gynecological infections, post-natal sepsis, septic abortion andendometritis. • Additional indications • Mixed aerobic and anaerobic soft tissue	i) same as Annexure A ii) Not approved	1. The Subcommittee noted that FDC of Ofloxacin 2mg + Ornidazole 5 mg per ml Infusion was approved by DCGI on 17.8.2009 for the treatment of diarrhoea of mixed infection in adult patients. 2. The FDC of Ofloxacin + Ornidazole injection was deliberated by NDAC (Antimicrobial, Antiparasitic, Antifungal & Antiviral) in its meeting held on 28.02.2014 . The Committee noted the recommendation of the Parliament Standing Committee (PSC) and evaluated this drug in present scenario. The firm presented the data of phase III trial data. The committee noted that parenteral use of antibacterial in acute diarrhoea is not recommended routinely. There is no specific advantage of giving Fluroquinolone and imidazole in parental form as both can be given individually, if indicated. The FDC will not be rationale. Hence, the committee did not recommend the FDC for continued marketing in India for the present approved indication of diarrhoea. The Subcommittee concurred with above comments from NDAC committee and noted that: 1. The list of indications is too wide and not specific ranging from intra-abdominal infections of bacterial (including anaerobic) and protozoal infections of different organ systems. The list includes mild and chronic infections like Giardiasis and sinusitis, otitis, CSOM, bacterial vaginosis, trichominiasis to more serious acute infections like septicemia, meningitis, peritonitis, post-operative wound infections. While the use of this injectable FDC for the milder and chronic infection cannot be justified, for treatment of the serious infections neither of the two ingredients or drugs of choice as per different recent guidelines including the national guideline in india (National treatment guidelines for antimicrobial use in infections disease version 1.0 2016 National centre for disease control Govt of India). 2. Ornidazole or ofloxacin can be given specific to etiology of the concerned disease, and the specific drug can be given individually. There is no scientific rationale to use them in an injectable FDC, which will increase its cost and there would be unnecessary exposure to either of ingredients thereby increasing ADR burden, promoting unnecessary injection use and with associated risks. Besides this would also promote resistance development. 3. Safety concers regarding misuse of this FDC containing Ofloxacin in paediatric patients. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S. No	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i. Indication as per package insert ii. If marketing anywhere	
	S.O.1852(E)	Ofloxacin + Ornidazole injection	Zuventus Healthcare Limited	Ofloxacin IP 200mg+ Ornidazole IP 500mg infusion	Normet is indicated for the treatment of diaarhoea of mixed infection in adult patients.	i) same as Annexure A ii) Not approved	1. The Subcommittee noted that FDC of Ofloxacin 2mg + Ornidazole 5 mg per ml Infusion was approved by DCGI on 17.8.2009 for the treatment of diarrhoea of mixed infection in adult patients. 2. The FDC of Ofloxacin + Ornidazole injection was deliberated by NDAC (Antimicrobial, Antiparasitic, Antifungal & Antiviral) in its meeting held on 28.02.2014 . The Committee noted the recommendation of the Parliament Standing Committee (PSC) and evaluated this drug in present scenario. The firm presented the data of phase III trial data. The committee noted that parenteral use of antibacterial in acute diarrhoea is not recommended routinely. There is no specific advantage of giving Fluroquinolone and imidazole in parental form as both can be given individually, if indicated. The FDC will not be rationale. Hence, the committee did not recommend the FDC for continued marketing in India for the present approved indication of diarrhoea. The Subcommittee concurred with above comments from NDAC committee and noted that: 1. Both the ingredients have different therapeutic indications. Having both, amoebic and bacterial diarrhoea coexisting is rare. 2. Ornidazole is effective against infective diarrhoea due to protozoal infection and this may encourage its indiscriminate use, particularly when combined with a fluoroquinolone like ofloxacin. This will enhance emergence of antimicrobial resistance against quinolones. 3. Safety concerns regarding misuse of this FDC containing Ofloxacin in paediatric patients. 4. This combination is not as per standard therapeutic guidelines There is no convincing scientific/ clinical evidence/ justification for the FDC.
	S.O.1852(E)	Ofloxacin + Ornidazole injection	Smilax Healthcare	Ofloxacin IP 200mg+ Ornidazole IP 500mg infusion	Broad Spectrum Antibiotic	i.Not Submitted ii.NA	1. The Subcommittee noted that FDC of Ofloxacin 2mg + Ornidazole 5 mg per ml Infusion was approved by DCGI on 17.8.2009 for the treatment of diarrhoea of mixed infection in adult patients. 2. The FDC of Ofloxacin + Ornidazole injection was deliberated by NDAC (Antimicrobial, Antiparasitic, Antifungal & Antiviral) in its meeting held on 28.02.2014 . The Committee noted the recommendation of the Parliament Standing Committee (PSC) and evaluated this drug in present scenario. The firm presented the data of phase III trial data. The committee noted that parenteral use of antibacterial in acute diarrhoea is not recommended routinely. There is no specific advantage of giving Fluroquinolone and imidazole in parental form as both can be given individually, if indicated. The FDC will not be rationale. Hence, the committee did not recommend the FDC for continued marketing in India for the present approved indication of diarrhoea. The Subcommittee perused the details submitted by the company: 1. The indication is not specified. There is no convincing scientific/ clinical evidence/ justification for the FDC.
346	S.O.1852(E)	Ofloxacin + Ornidazole injection	In view of the representation received and hearing given to the company, Recommendation and grounds/reasons for recommending prohibition/restriction/regulation: There is no therapeutic justification for this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.				

S. No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure -A (Provided By company)	i) Indication as per package insert ii) If marketing any where	
	S.O. 1853(E)	Fixed Dose Combinations Of Gemifloxacin + Ambroxol	-	-	-	-	The Subcommittee noted that FDC of Gemifloxacin + Ambroxol (320mg + 75mg SR) FC Tablets indicated for the treatment of lower respiratory tract infections in adult patients is approved by CDSCO on 24.12.08. The committee noted that the FDC of Gemifloxacin with Ambroxol was deliberated by SEC (Pulmonary) in its meeting held on 23-12-2015. The proposal of continued marketing of Gemifloxacin + Ambroxol was deliberated in current scenario. The Committee opined that Ambroxol being a mucolytic agent does not have any added advantage in the antimicrobial activity. Therefore the Committee considered the FDC as irrational in current scenario and did not recommend for its continued marketing. The DTAB Subcommittee concured with the opinion of SEC. There is no sound scientific/ clinical evidence/ justification for the FDC.
347	S.O. 1853(E)	Fixed Dose Combinations Of Gemifloxacin + Ambroxol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indicaiton as per Annexure -A (Provided By company)	i) Indicaiton as per package insert ii) If marketing any where	
	S.O. 1854E)	Fixed Dose Combinations Of Glucosamine+ Ibuprofen	-	-	-	-	The Subcommittee noted that this FDC was approved by DCG (I) on 03.11.2009 The FDC of Glucosamine with Ibuprofen was deliberated by SEC (Analgesic & Rheumatology) in its meeting held on 15.01.2016 as under: "The Committee reviewed the FDC for its continued marketing in the Country. Committee opined that glucosamine is required for long term use whereas Ibuprofen being NSAID is not recommended for long term. Thus the FDC would lead to unnecessary overuse of NSAID leading to toxicity. Further the FDC is also not approved Internationally. Hence the Committee did not recommend for its continued marketing." The Subcommittee concurred with the ten expert committee recommendations as above and further noted that: 1. There is no reasonable clinical evidence for benefit of Glucosamine. There is no sound scientific/ clinical evidence/ justification for the FDC.
348	S.O. 1854E)	Fixed Dose Combinations Of Glucosamine+ Ibuprofen	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **There is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.**				

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1855(E)	Etodolac + Paracetamol	Ipca	Etodolac IP 300mg/ 400mg + Paracetamol IP 325mg/ 325mg film coated tablet	for symptomatic treatment of acute pain and inflammation in patients, osteoarthritis, rheumatic arthritis & alkylosing spondylitis.	i) same ii) Not submitted	The Subcommittee noted that FDC of Etodolac 300mg + Paracetamol 500mg film coated tablet was approved by DCGI on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Also, Subcommittee noted that FDC of S (+) Etodolac 150/200/300mg + Paracetamol 500/500/500mg Tablets is approved by DCGI on 25.11.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The FDC of Etodolac + Paracetamol was deliberated by NDAC (Analgesics, Anesthetics & Rheumatology) in its meeting held on 19.02.2014. The NDAC commented as under: "The committee noted the recommendations of the PSC. The committee evaluated the safety and efficacy reports presented by the firm. The committee observed that the product shall not be prescribed more than 10 days as claimed by the firm. The committee opined that FDC is not required for short term use as Paracetamol can be prescribed separately when required and can be tapered off early if need arises. The committee recommended that the FDC is not rationale as present scenario." The Subcommittee noted the above comments and further noted that: 1. There is only one clinical study with ten day treatment duration, suggesting benefit of Paracetamol and Etodolac FDC over Etodolac alone in knee osteoarthritis. This study used Paracetamol 500 mg per tablet in combination with Etodolac 400mg. 2. There is no published sound/convincing scientific data on various indications mentioned by the appellant. 3. Also, standard treatment guidelines do not recommend use of this combination for the indications mentioned by the appellant. 4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1855(E)	Etodolac + Paracetamol	Lupin Ltd.	Etodolac iP 400mg+ Paracetamol 325mg film coated tablet	For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis	i)Not submitted ii) Not approved	The Subcommittee noted that FDC of Etodolac 300mg + Paracetamol 500mg film coated tablet is approved by DCGI on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Also, Subconmittee noted that FDC of S (+) Etodolac 150/200/300mg + Paracetamol 500/500/500mg Tablets is approved by DCGI on 25.11.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The FDC of Etodolac + Paracetamol was deliberated by NDAC (Analgesics, Anesthetics & Rheumatology) in its meeting held on 19.02.2014. The NDAC commented as under: "The committee noted the recommendations of the PSC. The committee evaluated the safety and efficacy reports presented by the firm. The committee observed that the product shall not be prescribed more than 10 days as claimed by the firm. The committee opined that FDC is not required for short term use as Paracetamol can be prescribed separately when required and can be tapered off early if need arises. The committee recommended that the FDC is not rationale as present scenario." The Subcommittee noted the above comments and further noted that: 1. There is only one clinical study with ten day treatment duration, suggesting benefit of Paracetamol and Etodolac FDC over Etodolac alone in knee osteoarthritis. This study used Paracetamol 500 mg per tablet in combination with Etodolac 400mg. 2. There is no published sound/convincing scientific data on various indications mentioned by the appellant. 3. Also, standard treatment guidelines do not recommend use of this combination for the indications mentioned by the appellant. 4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure-A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1855(E)	Etodolac + Paracetamol	Zuventus Healthcare	Etodolac iP 400mg+ Paracetamol 325mg film coated tablet	For acute and long-term use in the management of sign and symptoms of the following:osteoarthritis, rheumatic arthritis&alkylosing spondylitis.For management of acute pain and inflammation.	i) same ii) Not submitted	The Subcommittee noted that FDC of Etodolac 300mg + Paracetamol 500mg film coated tablet is approved by DCGI on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Also, Subcommittee noted that FDC of S (+) Etodolac 150/200/300mg + Paracetamol 500/500/500mg Tablets is approved by DCGI on 25.11.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The FDC of Etodolac + Paracetamol was deliberated by NDAC (Analgesics, Anesthetics & Rheumatology) in its meeting held on 19.02.2014. The NDAC commented as under: "The committee noted the recommendations of the PSC. The committee evaluated the safety and efficacy reports presented by the firm. The committee observed that the product shall not be prescribed more than 10 days as claimed by the firm. The committee opined that FDC is not required for short term use as Paracetamol can be prescribed separately when required and can be tapered off early if need arises. The committee recommended that the FDC is not rationale as present scenario." The Subcommittee noted the above comments and further noted that: 1. There is only one clinical study with ten day treatment duration, suggesting benefit of Paracetamol and Etodolac FDC over Etodolac alone in knee osteoarthritis. This study used Paracetamol 500 mg per tablet in combination with Etodolac 400mg. 2. There is no published sound/convincing scientific data on various indications mentioned by the appellant. 3. Also, standard treatment guidelines do not recommend use of this combination for the indications mentioned by the appellant. 4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1855(E)	Etodolac + Paracetamol	Emcure Pharmaceuticals	S(+) Etodolac 200mg+ Paracetamol IP 325mg uncoated tablet	For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis	i) Same ii) Not approved	The Subcommittee noted that FDC of Etodolac 300mg + Paracetamol 500mg film coated tablet is approved by DCGI on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Also, Subcommittee noted that FDC of S (+) Etodolac 150/200/300mg + Paracetamol 500/500/500mg Tablets is approved by DCGI on 25.11.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The FDC of Etodolac + Paracetamol was deliberated by NDAC (Analgesics, Anesthetics & Rheumatology) in its meeting held on 19.02.2014. The NDAC commented as under: "The committee noted the recommendations of the PSC. The committee evaluated the safety and efficacy reports presented by the firm. The committee observed that the product shall not be prescribed more than 10 days as claimed by the firm. The committee opined that FDC is not required for short term use as Paracetamol can be prescribed separately when required and can be tapered off early if need arises. The committee recommended that the FDC is not rationale as present scenario." The Subcommittee noted the above comments and further noted that: 1. There is only one clinical study with ten day treatment duration, suggesting benefit of Paracetamol and Etodolac FDC over Etodolac alone in knee osteoarthritis. This study used Paracetamol 500 mg per tablet in combination with Etodolac 400mg. 2. There is no published sound/convincing scientific data on various indications mentioned by the appellant. 3. Also, standard treatment guidelines do not recommend use of this combination for the indications mentioned by the appellant. 4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1855(E)	Etodolac + Paracetamol	Mankind Pharma	Etodolac IP 400mg+ Paracetamol IP 325mg film coated tablets	Mild to moderate pain e.g. headache, muscle aches, backache, toothache, cold. Also for the treatment of osteoarthritis, rheumatic arthritis and gout. Control Fever (high temperature, known as pyrexia) e.g. some one has flu (influenza)	i) Same ii) Not approved	The Subcommittee noted that FDC of Etodolac 300mg + Paracetamol 500mg film coated tablet is approved by DCGI on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Also, Subcommittee noted that FDC of S (+) Etodolac 150/200/300mg + Paracetamol 500/500/500mg Tablets is approved by DCGI on 25.11.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The FDC of Etodolac + Paracetamol was deliberated by NDAC (Analgesics, Anesthetics & Rheumatology) in its meeting held on 19.02.2014. The NDAC commented as under: "The committee noted the recommendations of the PSC. The committee evaluated the safety and efficacy reports presented by the firm. The committee observed that the product shall not be prescribed more than 10 days as claimed by the firm. The committee opined that FDC is not required for short term use as Paracetamol can be prescribed separately when required and can be tapered off early if need arises. The committee recommended that the FDC is not rationale as present scenario." The Subcommittee noted the above comments and further noted that: 1. There is only one clinical study with ten day treatment duration, suggesting benefit of Paracetamol and Etodolac FDC over Etodolac alone in knee osteoarthritis. This study used Paracetamol 500 mg per tablet in combination with Etodolac 400mg. 2. There is no published sound/convincing scientific data on various indications mentioned by the appellant. 3. Also, standard treatment guidelines do not recommend use of this combination for the indications mentioned by the appellant. 4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1855(E)	Etodolac + Paracetamol	JK Print Packs	Etodolac iP 400mg+ Paracetamol 325mg film coated tablet	Mild to moderate pain e.g. headache, muscle aches, backache, toothache, cold. Also for the treatment of osteoarthritis, rheumatic arthritis and gout. Control Fever (high temperature, known as pyrexia) e.g. some one has flu (influenza)	i) same ii) Not submitted	The Subcommittee noted that FDC of Etodolac 300mg + Paracetamol 500mg film coated tablet is approved by DCGI on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Also, Subcommittee noted that FDC of S (+) Etodolac 150/200/300mg + Paracetamol 500/500/500mg Tablets is approved by DCGI on 25.11.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The FDC of Etodolac + Paracetamol was deliberated by NDAC (Analgesics, Anesthetics & Rheumatology) in its meeting held on 19.02.2014. The NDAC commented as under: "The committee noted the recommendations of the PSC. The committee evaluated the safety and efficacy reports presented by the firm. The committee observed that the product shall not be prescribed more than 10 days as claimed by the firm. The committee opined that FDC is not required for short term use as Paracetamol can be prescribed separately when required and can be tapered off early if need arises. The committee recommended that the FDC is not rationale as present scenario." The Subcommittee noted the above comments and further noted that: 1. There is only one clinical study with ten day treatment duration, suggesting benefit of Paracetamol and Etodolac FDC over Etodolac alone in knee osteoarthritis. This study used Paracetamol 500 mg per tablet in combination with Etodolac 400mg. 2. There is no published sound/convincing scientific data on various indications mentioned by the appellant. 3. Also, standard treatment guidelines do not recommend use of this combination for the indications mentioned by the appellant. 4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.

S.No.	Prohibition Notification No.	Name of FDC as per banning list	Information presented by company in Annexure-A				Grounds/reasons for attracting one of the three factors (risks, therapeutic value & justification of ingredients in the FDCs) based on documents submitted and hearing given to the appellants (where applicable) including AIDAN and other information available and analysed
			Name of the Firm	Product and Dosage form	Indication as per Annexure - A (Provided By company)	i. Indication as per package insert ii. Marketing anywhere	
	S.O. 1855(E)	Etodolac + Paracetamol	Wanbury	Etodolac IP 400mg+ Paracetamol 325mg film coated tablet	Etosafe P is indicated in treatment of acute painful inflammatory conditions such as osteoarthritis flare up, post operative pain, trauma, strain and sprain.	i)same ii) Not submitted	The Subcommittee noted that FDC of Etodolac 300mg + Paracetamol 500mg film coated tablet is approved by DCGI on 20.10.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Also, Subcommittee noted that FDC of S (+) Etodolac 150/200/300mg + Paracetamol 500/500/500mg Tablets is approved by DCGI on 25.11.2009 for the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The FDC of Etodolac + Paracetamol was deliberated by NDAC (Analgesics, Anesthetics & Rheumatology) in its meeting held on 19.02.2014. The NDAC commented as under: "The committee noted the recommendations of the PSC. The committee evaluated the safety and efficacy reports presented by the firm. The committee observed that the product shall not be prescribed more than 10 days as claimed by the firm. The committee opined that FDC is not required for short term use as Paracetamol can be prescribed separately when required and can be tapered off early if need arises. The committee recommended that the FDC is not rationale as present scenario." The Subcommittee noted the above comments and further noted that: 1. There is only one clinical study with ten day treatment duration, suggesting benefit of Paracetamol and Etodolac FDC over Etodolac alone in knee osteoarthritis. This study used Paracetamol 500 mg per tablet in combination with Etodolac 400mg. 2. There is no published sound/convincing scientific data on various indications mentioned by the appellant. 3. Also, standard treatment guidelines do not recommend use of this combination for the indications mentioned by the appellant. 4. Patients may not need both the ingredients simultaneously and use of this FDC may lead to unnecessary exposure to other ingredient and its side effects. There is no convincing scientific/ clinical evidence/ justification for the FDC.
349	S.O. 1855(E)	Etodolac + Paracetamol	**Recommendation and grounds/reasons for recommending prohibition/restriction/regulation:** **The FDC may involve risk to human beings.** **Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940.** **In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended**				

5. Bibliography

Textbooks and Guidelines

1. Brunton LL, Chabner BA, Knolmann (Eds.) Goodman & Gilman's The Pharmacological Basis of Therapeutics, 12th edition, New York, McGraw Hill, 2011
2. Brunton LL, Hilal-Dandan R, Knollmann BC (Eds.). Goodman & Gilman's The Pharmacological Basis of Therapeutics. 13th ed. New York: McGraw Hill education, 2018
3. Katzung BG. Basic and Clinical Pharmacology; 14th ed. USA: McGraw Hill Education, 2018
4. Rang HP, Ritter JM, Flower RJ, Henderson G. Rang and Dale's Pharmacology, 8th ed., London: Elsevier Ltd, 2016
5. Satoskar RS, Rege NN, Tripathi RK, Bhandarkar SD. Pharmacology & Pharmacotherapeutics, 25th ed. Mumbai: Elsevier and Popular Prakashan, 2017
6. Tripathi KD. Essentials of Medical Pharmacology, 7th ed. New Delhi: Jaypee Brothers Medical Publishers, 2013
7. Basic & Clinical Pharmacology, Katzung BG (Ed.), 12th Edn., New York, McGraw Hill, 2012
8. World Health Organization. WHO Technical Report Series, No. 929, 2005, Annex 5 Guidelines for registration of fixed-dose combination medicinal products. [Available at: http://www.who.int/medicines/areas/quality_safety/quality_assurance/GuidelinesRegistrationFixedDoseCombinationTRS929Annex5.pdf]
9. CFR- Code of Federal Regulations Title 21 [Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=341&showFR=1]
10. Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India 2013, Policy Guidelines For Approval of Fixed Dose Combinations (FDCs) in India. [Available at: http://www.cdsco.nic.in/writereaddata/Report%20of%20Dr.C.K%20Kokate.pdf]
11. Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India 2010, Guidance For Industry On Fixed Dose Combinations (FDCs). [Available at: http://www.cdsco.nic.in/writereaddata/FDC%20Guidelines%20_%20Revised1.pdf]
12. European Medical Agency. Guideline on clinical development of fixed combination medicinal products, 2017, EMA/CHMP/158268/2017 Committee for Human Medicinal Products (CHMP). [Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500224836.pdf]
13. European Medical Agency. Guideline on clinical development of fixed combination medicinal products, 2015, EMA/CHMP/281825/2015, Committee for Human Medicinal Products (CHMP). [Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/05/WC500186840.pdf]
14. Products authorised for use in children up to 6 years of age which can be sold as before. [Available at: http://news.bbc.co.uk/2/shared/bsp/hi/pdfs/27_03_08medicine.pdf]
15. Government of the People's Republic of Bangladesh, Directorate of Drug Administration, Ministry of Health and Population Control, 1982
16. Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh, 2005
17. Relevant references from Legal database manupatra for Supreme Court and High Court cases that concerned Section 26A: (a) MANU/PH/0031/1993; (b) MANU/SC/0056/1994; (c) MANU/KA/1498/2013; (d) MANU/DE/005412001

Endocrinology

18. Rajagopalan S, et al. Effect of low dose pioglitazone on glycemic control and insulin resistance in type 2 diabetes: A randomized, double blind, clinical trial. Diabetes Res Clin Pract 2015; 109(3):e32-e35 [Available at: https://www.diabetesresearchclinicalpractice.com/article/S0168-8227(15)00260-0/fulltext]
19. Balaji V. Efficacy and safety of pioglitazone in type 2 diabetes in the Indian patients: Results of an observational study. Indian Journal of Endocrinoloy and Metabolism. 2013; 7(4):709-15
20. Mohan V, et al. Pioglitazone-where do we stand in India? J Assoc Physicians India 2012; 60(1):68-70.
21. Panikar VK, et al. Effect of Low (7.5 mg/day), Standard (15 mg/ day) and High (30 mg/day) Dose Pioglitazone Therapy on Glycemic Control and Weight Gain in Recently-Diagnosed Type 2 Diabetes Patients. J Assoc Physicians India 2015(11):36-39
22. Karla S, et al. Recent Advances in Endocrinology. J Pak Med Assoc 2015; 65(3):333-5
23. Yanaia H, et al. The Low-Dose (7.5 mg/day) Pioglitazone Therapy, J Clin Med Res 2017; 9(10): 821–825.
24. Adachi H, et al. The low dose (7.5 mg/day) pioglitazone is beneficial to the improvement in metabolic parameters without weight gain and an increase of risk for heart failure. Int J Cardiol 2017; 227:247-8.
25. Aoki Y. Effects of Low-Dose Pioglitazone on Serum Levels of Adiponectin, Dehydroepiandrosterone, Amyloid Beta Peptide, and Lipid Profile in Elderly Japanese People with Type 2 Diabetes. Advances in Endocrinology 2015; Article ID 782530
26. Majima T, et al. Safety and efficacy of low-dose pioglitazone (7.5 mg/day) vs. standard-dose pioglitazone (15 mg/day) in Japanese women with type 2 diabetes mellitus., Endocr J. 2006; 53(3):325-30.
27. Moses ACR et al., Triple oral fixed dose combination of glimepiride, metformin and low dose (7.5 mg) pioglitazone in the treatment of uncontrolled type 2 diabetes –International Journal Of Basic Medical Sciences 2013; [Available at: http://www.jbms.com].
28. Glucophage. Metformin Hydrochloride. [Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020357s037s039,021202s021s023lbl.pdf]
29. Korhonen P, et al. Pioglitazone use and risk of bladder cancer in patients with type 2 diabetes: retrospective cohort study using datasets from four European countries, BMJ 2016;354:i3903.
30. Charpentier G, et al. Earlier triple therapy with pioglitazone in patients with type 2 diabetes, Diabetes Obes Metab 2009;11(9):844-54.
31. Gohel S, et al. Therapeutic Potential of Fixed Dose Combinations Of Drugs For Type 2 Diabetes Mellitus. World Journal of Pharmacy And Pharmaceutical Sciences 2015; 4(06):202-215.
32. John M, et al. Triple fixed drug combinations in type 2 diabetes, Indian Journal of Endocrinology and Metabolism 2015; 19:311-313.
33. Bailey CJ, et al. Fixed dose single tablet antidiabetic combinations. Diabetes Obesity and Metabolism 2009; 11:527-533.
34. Vjaykumar TM, et al. Safety, Efficacy, and Bioavailability of Fixed-Dose Combinations in Type 2 Diabetes Mellitus: A Systematic Updated Review. Curr Ther Res Clin Exp 2017; 84:4–9.
35. Jabbour S, et al. Advantages of Extended-Release Metformin in Patients with Type 2 Diabetes Mellitus. Clinical Focus: Metabolic Disorders, Diabetes and Cardiovascular Disease 2011; 123(1):15-23
36. Roberts VL, et al. Triple therapy with glimepiride in patients with type 2 diabetes mellitus inadequately controlled by metformin and a thiazolidinedione: results of a 30-week, randomized, double-blind, placebo-controlled, parallel-group study. Clin Ther 2005; 27(10):1535-47.
37. **E20:** International Diabetes Foundation. IDF Clinical Practice Recommendations for managing Type 2 Diabetes in Primary Care -2017. [Available at: www.idf.org/managaing-type2-diabetes]
38. American Diabetes Association. Pharmacologic approaches to glycemic treatment: Standards of Medical Care in Diabetes 2018. Diabetes Care 2018; 41 (sup 11): S1-S2.
39. Bajaj S, et al. RSSDI Clinical Practice Recommendations for Management of Type 2 Diabetes Mellitus 2017. Int J Diabetes Dev Ctries 2018; 78(Supp 11):S1-S115
40. ICMR Guidelines for management of type 2 diabetes 2018. [Available at: http://www.icmr.nic.in/guide/cancer/diabetes2018.pdf]
41. Ting RZ-Wet al. Risk Factors of Vitamin B12 Deficiency in Patients Receiving Metformin. Arch Intern Med 2006; 166:1975-9
42. Olt S, et al. Investigation of the vitamin B12 deficiency with peripheral neuropathy in patients with type 2 diabetes mellitus treated using Metformin, North Clin Istanb 2017; 4(3):233–236.
43. Anil Kumar R, et al. Prevalence of vitamin B12 deficiency in Indian type 2 diabetes subjects on Metformin therapy, International Journal of Medical Research and Review 2017; 5(9):845-50
44. Garber AJ, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm– 2017. Endocrine Practice 2017; 23(2):207-238
45. Garber AJ, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm- 2018 Executive Summary. Endocrine Practice 2018; 24(1):91-120
46. Einhorn D, et al. Pioglitazone hydrochloride in combination with Metformin in the treatment of type 2 diabetes mellitus: a randomized placebo-controlled study. Clinical Therapeutics 2000; 22(12): 1395-1407
47. Kaku K. Efficacy and safety of therapy with metformin plus pioglitazone in the treatment of patients with type 2 diabetes: a double-blind, placebo-controlled, clinical trial, Current Medical Research and opinion 2009; 25:1111–1119.
48. Bell DSH, et al. Long-term efficacy of triple oral therapy for type 2 diabetes mellitus. Endocrine Practice 2002; 8:271-5

49. American Diabetes Association. Standards of Medical Care in Diabetes 2016. Diabetes Care 2016; 39(Suppl 1): S1-S112.
50. Yanai H, et al. The low dose (7.5mg/day) Pioglitazone therapy. J Clin Med Res 2017; 9(10): 821-825.
51. Rajagopalan S, et al. Effect of low dose pioglitazone on glycemic control and insulin resistance in Type 2 diabetes: A randomized, double blind, clinical trial. Diabetes Research and Clinical Practice 2015; 109(3):e32-5
52. Naganjani ChV, et al. Comparative Study of Effects of Combination of Metformin + Glimepiride Vs Metformin + Glimepiride + Pioglitazone in Type 2 Diabetes Mellitus Patients. Int J Pharm Bio Sci 2014; 5(1): (P)212– 218.
53. de Jager J, et al., Long term treatment with metformin in patients with type 2 diabetes and risk of vitamin B-12 deficiency: randomised placebo controlled trial. BMJ 2010; 340: c2181.
54. Bedford M. Fixed-dose combination of antidiabetic therapy: Real-world factors associated with prescribing choices and relationship with patient satisfaction and compliance. Adv Ther 2012; 29(1):26-40
55. American Diabetes Association. Standards of Medical Care in Diabetes 2016. Abridged for Primary Care Providers. Clinical Diabetes Journals 2016; 34(1):3-21
56. Scheen AJ, et al. Long-term glycaemic control with metformin-sulphonylurea-pioglitazone triple therapy in PROactive (PROactive 17). Diabetes Medicine 2009; 26:1033-1039.
57. Kaur K, et al. Comparison of efficacy of add-on therapy of vildagliptin versus pioglitazone among Type 2 Diabetes Mellitus patients inadequately controlled on dual therapy of metformin plus sulfonylurea. Asian Journal of Medical Sciences 2014; 5(3):77-81.
58. Gupta S, et al. Comparison of the effect of Glitazones and DPP-IV Inhibitors in type 2 diabetes as add on therapy on insulin sensitivity and serum hs-CRP Levels. JK Science 2013; 15(2):69-72.
59. Liu SC, et al. Efficacy and Safety of Adding Pioglitazone or Sitagliptin to Patients with Type 2 Diabetes Insufficiently Controlled with Metformin and a Sulfonylurea. Endocrine Practice 2013; 19(6):980-8.
60. Heurtier A, et al. Effects of bed-time insulin versus pioglitazone on abdominal fat accumulation, inflammation and gene expression in adipose tissue in patients with type 2 diabetes, Diabetes Research and Clinical Practice 2009; 86:37-43.
61. Sultana G, et al. Drug utilization of oral hypoglycemic agents in a university teaching hospital in India. J Clin Pharm Ther 2010; 35:267-77.
62. Paneerselvam. A et al., A retrospective multicentric study evaluating the effectiveness and safety of pioglitazone combination therapy in Indian type 2 diabetic patients. Br J Med Health Res 2016; 3(9):80-92.
63. Meshram DM, et al. Evaluation of efficacy and safety of fixed dose combination of glimepiride 2 mg pluspioglitazone 15 mg plus metformin SR 500 mg in the management of patients with type-2 diabetes mellitus. J Indian Med Assoc 2005;103(8):447-50.
64. Jindal A, et al. Comparative evaluation of voglibose versus pioglitazone on glycaemic control and lipid profile in patients of type 2 diabetes mellitus on glimepiride and metformin in Punjabi population. Int J Basic Clin Pharmacol 2012; 1(3):160-7.
65. Bell DS, et al. Triple oral fixed-dose diabetes polypill versus insulin plus metformin efficacy demonstration study in the treatment of advanced type 2 diabetes (TrIED study-II). Diabetes, Obesity and Metabolism 2011; 13(9):800-805
66. Moses ACR, et al. Triple oral fixed dose combination of Glimepiride + Metformin SR + Pioglitazone Vs Insulin 70/30 Mix + Metformin SR Efficacy Demonstration study in the treatment of insulin-naïve patients with type 2 diabetes mellitus inadequately controlled on dual therapy of Glimepiride + Metformin prescribed separately or as FDC. (TrIED study). Indian Pract 2018; 61(12):776-85
67. Panikar V, et al. Beneficial Effects of Triple Drug Combination of Pioglitazone with Glibenclamide and Metformin in Type 2 Diabetes Mellitus Patients on Insulin Therapy. J Assoc Physicians India. 2003; 51(11):1061-4.
68. Aso Y. Low dose pioglitazone increases serum high molecular weight adiponectin and improves glycemic control in Japanese patients with poorly controlled type 2 diabetes. Diab Res Clin Pract 2009; 85:147-52
69. Faruqui AA. Safety and efficacy of Fixed Dose combination of voglibose, glimepiride and metformin in Indian type 2 diabetes mellitus patients. Adv Diabetes Metab 2016; 4(3):49-54

Analgesics and anti-inflammatory drugs

70. Blondell RD, et al. Pharmacologic Therapy for Acute Pain. Am Fam Physician 2013; 87(11):766-72
71. European Medicines Agency Press Office. Press Release European Medicines Agency recommends restricted use of nimesulide-containing medicinal products. 2007. [Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2009/11/WC500011199.pdf] Doc. Ref. EMEA/432604/2007
72. Antonaci F, et al. A review of current European treatment guidelines for migraine. J Headache Pain 2010; 11:13–19.
73. United Nations. Consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by governments, twelfth issue, Pharmaceuticals, 2005 Pp 1- 597 [Available at: http://apps.who.int/medicinedocs/documents/s16780e/s16780e.pdf]
74. Davis A. et al. The dangers of NSAIDs: look both ways. British Journal of General Practice 2016; 66(645): 172-173.
75. Ortho-McNeil-Janssen Pharmaceuticals, Inc. Highlights of Prescribing Information. Tradename (tapentadol) immediate release oral tablets, 2008. Pp 1-27. [Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022304s000lbl_v2.pdf
76. Hiller A, et al. Propacetamol and Diclofenac alone and in combination for analgesia after elective tonsillectomy. Acta Anaesthesiol Scand 2004;48:1185—1189.
77. McAlindon TE, et al. Glucosamine and chondroitin for treatment of osteoarthritis A systematic quality assessment and meta-analysis. JAMA 2000; 283:1469-1475.
78. Towheed T, et al. Glucosamine therapy for treating osteoarthritis (Review). The Cochrane Library 2009; Issue 2:1-77.
79. Butawan M, et al. Methylsulfonyl methane: Applications and Safety of a Novel Dietary Supplement, Nutrients, 2017; 9: 290.
80. Brien S, et al. Systematic review of the nutritional supplements dimethyl sulfoxide (DMSO) and methylsulfonyl methane (MSM) in the treatment of Osteoarthritis, Osteoarthritis and Cartilage 2008; 16:1277-88
81. Jones AL, et al. Should methionine be added to every paracetamol tablet? BMJ 1997; 315: 301–3
82. Roman- Blas JA, et al. Combined Treatment With Chondroitin Sulfate and Glucosamine Sulfate Shows No Superiority Over Placebo for Reduction of Joint Pain and Functional Impairment in Patients With Knee Osteoarthritis A Six-Month Multicenter, Randomized, Double-Blind, Placebo-Controlled Clinical Trial. Arthritis and Rheumatology 2017; 69(1):77–85.
83. Darvish H, et al. Analgesic Efficacy of Diclofenac and Paracetamol vs. Meperidine in Caesarean Section. Anesthesiology and Pain Medicine 2014; 4(1):e9997. [Available at: http://anesthpain.com/en/articles/17346.html]
84. US Food and Drug Administration. FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure [Available at: https://www.fda.gov/drugs/drugsafety/ucm239821.htm]
85. Gwee KA, et al. Coprescribing proton-pump inhibitors with nonsteroidal anti-inflammatory drugs: risks versus benefits. Journal of Pain Research 2018; 11:361–374.
86. Panagariya A, et al. A preliminary trial of serratiopeptidase in patients with carpal tunnel syndrome. J Assoc Physicians India 1999; 47(12):1170-2.
87. Ingle P, et al. Evaluation of symptomatic efficacy and safety of diclofenac versus etrocoxib in combination with serratiopeptidase in knee osteoarthritis. Pharmagene 2014; 1(4):10-14.
88. Fujimori S. What are the effects of proton pump inhibitors on the small intestine? World J Gastroenterol 2015; 21(22):6817-6819.
89. Washio E, et al. Proton Pump Inhibitors Increase Incidence of Nonsteroidal Anti-Inflammatory Drug–Induced Small Bowel Injury: A Randomized, Placebo-Controlled Trial. Clinical Gastroenterology and Hepatology 2016; 14:809–815.
90. Yuan JQ, et al, Systematic review with network meta-analysis: comparative effectiveness and safety of strategies for preventing NSAID-associated gastrointestinal toxicity. Aliment Pharmacol Ther 2016; 43:1262–1275.
91. Parcek A. et al. A randomized, multicentric, comparative evaluation of aceclofenac–paracetamol combination with Aceclofenac alone in Indian patients with osteoarthritis flare-up. Expert Opin. Pharmacother 2009; 10(5):727-735.
92. Cliff KS, et al. Combining Paracetamol (Acetaminophen) with Non steroidal Anti inflammatory Drugs: A Qualitative Systematic Review of Analgesic Efficacy for Acute Postoperative Pain, Anesth Analg 2010; 110:1170–1179.
93. Witenko C, et al. Considerations for the Appropriate Use of Skeletal Muscle Relaxants for the Management of Acute Low Back Pain. Pharmacy and Therapeutics 2014; 39(6):427-435.
94. Hyllested M, et al. Comparative effect of Paracetamol, NSAIDs or their combination in postoperative pain management: a qualitative review. British Journal of Anaesthesia 2002; 88(2): 199-214.
95. Pathan SA, et al. A Systematic Review and Meta-analysis Comparing the Efficacy of Nonsteroidal Anti-inflammatory Drugs, Opioids, and Paracetamol in the Treatment of Acute Renal Colic, Eur Urol. 2018; 73(4):583-595.
96. Afshar K, et al. Non-steroidal anti-inflammatory drugs (NSAIDs) and non-opioids for acute renal colic. Cochrane Database Syst Rev. 2015; Issue 6:CD006027.

97. Lefebvre G et al. Primary Dysmenorrhea Consensus Guideline. SOGC Clinical Practice Guideline. Journal of Obstetrics and Gynecology Canada 2005;1117-1130.
98. Burnett M, et al. No. 345 Primary Dysmenorrhea Consensus Guideline. Journal of Obstetrics and Gynecology Canada 2017; 39(7):585-595
99. Siddik SM, et al. Diflofenceac and/ or propacetamol for post-operative pain management after Caesarean delivery in patients receiving patient-controlled analgesia morphine Reg Anesth Pain Med 2001; 26(4):310-5
100. Gebeyehu MB, et al. Prevalence, Impact, and Management Practice of Dysmenorrhea among University of Gondar Students, North western Ethiopia: A Cross-Sectional Study. International Journal of Reproductive Medicine 2017; 2017:3208276. [Available at: https://www.hindawi.com/journals/ijrmed/2017/3208276/]
101. Osayande AS, et al. Diagnosis and Initial Management of Dysmenorrhea. Am Fam Physician 2014; 89(5):341-346
102. Calapai G, et al. Systematic Review of Tranexamic Acid Adverse Reactions. J Pharmacovigilance 2015; 3:4
103. Lacovides S, et al. What we know about primary dysmenorrhea today: a critical review. Human Reproduction Update 2015; 21:762-778.
104. Kierch TA, et al. The Onset of Action and the Analgesic Efficacy of Saridon®* (a Propyphenazone/ Paracetamol/ Caffeine Combination) in Comparison with Paracetamol, Ibuprofen, Aspirin and Placebo (Pooled Statistical Analysis). Current Medical Research and Opinion 2001; 19(1): 19-25
105. National Institute of Health and care Excellence (NICE). Migraine (Last updated February 2018)
106. National Pharmaceutical Council. Management of Acute Pain and Chronic Non cancer Pain. In: Pain: Current Understanding of assessment, management and treatments Pp 61-71
107. Hochberg MC, et al. American College of Rheumatology 2012 recommendations for the use of non pharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care and Research 2012; 6(4):465-74.
108. Buescher JJ, et al. Do acetaminophen and an NSAID combined relieve osteoarthritis pain better than either alone? J Fam Pract 2004; 53(6):501-3.
109. South West Regional Wound Care Toolkit. B.5.3. WHO Pain Ladder with pain management guidelines. [Available at: http://www.southwesthealthline.ca/healthlibrary_docs/B.5.3.WHOPainLadder.pdf]
110. American Association of Orthopedic Surgeons. Treatment of Osteoarthritis of the Knee, Evidence-based guidelines, 2nd edition, 2013 [Available at: https://www.aaos.org/research/guidelines/treatmentofosteoarthritisoftheknee guideline.pdf]
111. Akyel A, et al. Acute inferior myocardial infarction with low atrial rhythm due to Propyphenazone: Kounis syndrome. Int J Cardiol 2010; 148(3):352–353
112. MacRae F, et al. How to change NSAID prescribing. The Pharmaceutical Journal 2004; 272: 249-52
113. Gor AP, et al. Adverse drug reactions of nonsteroidal anti-inflammatory drugs in orthopedic patients. J Pharmacol Pharmacother 2011, 2(1):26–29.
114. Doepker C, et al. Caffeine: Friend or Foe? Annu Rev Food Sci Technol 2016; 7:6.1–6.21
115. Goldstein J. Caffeine as an analgesic adjuvant, Inflammmopharmacology 2001; 9:51–61.
116. Laska EM, et al. Effect of caffeine on acetaminophen analgesia. Clin Pharmacol Ther 1983; 33(4):498-509
117. Laska EM, et al. Caffeine as an analgesic adjuvant. JAMA 1984; 251(13): 1711-18
118. McLellan TM, et al. A review of caffeine's effects on cognitive, physical and occupational performance. Neuroscience and Behavioral Review. 2016; 71:294-312
119. Marmura MJ, et al. The Acute Treatment of Migraine in Adults: The American Headache Society Evidence Assessment of Migraine Pharmacotherapies. Headache 2015; 55:3-20
120. Onakpoya IJ, et al. Worldwide withdrawal of medicinal products because of adverse drug reactions: a systematic review and analysis. Critical Reviews in Toxicology 2016; 46(6):477-89
121. Onakpoya IJ, et al. Post-marketing withdrawal of 462 medicinal products because of adverse drug reactions: a systematic review of the world literature, BMC Medicine 2016 14:10
122. Greenhalgh T. Assessing the methodological quality of published papers. BMJ 1997; 315(7013):305-308
123. Sampathkumar K, et al. Analgesic nephropathy- a painful progression. Crit Med Insights Urology 2016; 9:7-10
124. Graham DY, et al. Risks and gastroprotective strategies: Current status and future. Gastroenterology 2008; 134:1240-57
125. Rafaniello C. Risk of gastrointestinal complications associated to NSAIDS, low-dose aspirin and their combinations; results of pharmacovigilance reporting system. Pharmacol Res 2016; 104:108-14
126. Department of Economic and Social Affairs. Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments. Fourteenth Issue (New data only) (January 2005 – October 2008). Pharmaceuticals, New York, United Nations 2009 [Available at: http://apps.who.int/medicinedocs/documents/s16779e/s16779e.pdf]

General Medicine

127. National Centre for Disease Control, Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India. National Treatment Guidelines for Antimicrobial Use in Infectious Disease 2016, Version 1.0, (2016) 1-64.
128. Scottish Intercollegiate Guidelines Network Part of NHS Quality Improvement Scotland: Management of sore throat and indications for tonsillectomy. A national clinical guideline, 2010, Pp 1-37. [Available at: http://www.sign.ac.uk/assets/sign117.pdf]
129. World Health Organization. WHO Guidelines for The treatment of Chlamydia trachomatis. Geneva, World Health Organization 2016; Pp 1-44. [Available at: http://apps.who.int/iris/bitstream/handle/10665/246165/9789241549714-eng.pdf?sequence=1]
130. World Health Organization. WHO Guidelines for the Treatment of Neisseria Gonorrhoea. 2016. 1-55. [Available at: http://apps.who.int/iris/bitstream/handle/10665/246114/9789241549691-eng.pdf?sequence=1]
131. Stevens DL. et al., Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America. Clinical Infectious Diseases; 2014, 59(2): e10–e52.
132. Indian Council of Medical Research. Treatment Guidelines for Antimicrobial Use in Common Syndromes. New Delhi, Indian Council of Medical Research, Department of Health Research, Government of India 2017. 1-73.
133. Gupta D, et al. for the Pneumonia Guidelines Working Group, Guidelines for diagnosis and management of community-and hospital-acquired pneumonia in adults, Joint ICS/ NCCP(I) recommendations. Lung India 2012 (suppl.2) s27-s62.
134. Paul UK. Typhoid Fever – Recent Management, 64-67 [Available at: http://www.apiindia.org/pdf/medicine_update_2017/mu_015.pdf]
135. Divatia JV, Todi SK (Eds.), Principles of initial empirical antimicrobial therapy in patients with severe sepsis and septic shock in the intensive care units. In: Treatment Guidelines for Antimicrobial Use in Common Syndromes. New Delhi, Indian Council of Medical Research, Department of Health Research, Government of India 2017, Pp 74-87.
136. Mathur P, et al. (Eds), Antimicrobial guidelines for prophylaxis and treatment of surgical site infections. In: Treatment Guidelines for Antimicrobial Use in Common Syndromes. New Delhi, Indian Council of Medical Research, Department of Health Research, Government of India 2017, Pp 88-97.
137. Wig N, et al. (Eds), Antimicrobial Guidelines for Upper respiratory tract infections. In: Treatment Guidelines for Antimicrobial Use in Common Syndromes. New Delhi, Indian Council of Medical Research, Department of Health Research, Government of India 2017, Pp 98-101.
138. Wig N et al. (Eds), Antimicrobial Guidelines for Urinary tract infections. In: Treatment Guidelines for Antimicrobial Use in Common Syndromes. New Delhi, Indian Council of Medical Research, Department of Health Research, Government of India 2017, Pp 102-106.
139. Morbidity and mortality weekly report (MMWR) and Update to CDC's sexually transmitted diseases Treatment Guidelines, 2010: Oral Cephalosporins No Longer a Recommended Treatment for Gonococcal Infections, 2012: 61(31):590-594.
140. Heart Foundation. Cardiac Society of Australia and New Zealand. Sore throat [Available at: https://www.heartfoundation.org.nz/resources/a-guide-for-sore-throat-management-algorithm
141. Athlin S, et al. Management of community-acquired pneumonia in immune competent adults: updated Swedish guidelines 2017. Infectious Diseases 2017; Pp 1–26 [Available at: http://dx.doi.org/10.1080/23744235.2017.1399316]
142. Workowski KA, et al. Sexually Transmitted Diseases Treatment Guidelines, 2010 Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report 2010; 59:1-110.
143. Upadhyay R, et al. API Recommendations for the Management of Typhoid Fever. J Assoc Physicians India 2015, 63(11):77-96.
144. Workowsky KA, et al. Morbidity and Mortality Weekly Report (MMWR), Sexually Transmitted Diseases Treatment Guidelines, 2015; 64: 1-137.
145. Department of AIDS control, Ministry of Health and Family Welfare, Government of India. National Guideline on prevention, management and control of reproductive tract infections of sexually transmitted infections 2014, Pp 1-148.
146. Senok AC et al. Probiotics for the treatment of bacterial Vaginosis. Cochrane Database Systematic Review 2009; Issue 4:CD006289.

147. Wormser GP, et al. The clinical assessment, treatment, and prevention of Lyme disease, human granulocytic anaplasmosis, and babesiosis: Clinical practice guidelines by the Infectious Diseases Society of America. Clinical Infectious Diseases 2006; 43:1089-1134
148. Costelloe C, et al. Effect of antibiotic prescribing in primary care on antimicrobial resistance in individual patients: systematic review and meta-analysis BMJ; 2010: 340, c2096 (1-11)
149. Bronzwaer SLAM, et al. The Relationship between Antimicrobial Use and Antimicrobial Resistance in Europe Emerging Infectious Diseases 2002; 8(2):278-282.
150. Bell BG, et al. A systematic review and meta-analysis of the effects of antibiotic consumption on antibiotic resistance BMC Infectious Diseases 2014; 14:13 1-25.
151. Dancer SJ. The problem with cephalosporins. Journal of antimicrobial chemotherapy 2001, 48: 463-478.
152. Davies J, et al. Origins and Evolution of Antibiotic Resistance, Microbiology and Molecular Biology Reviews 2010; 74(3):417–433.
153. Woodhead M, et al, Guidelines for the management of adult lower respiratory tract infections Eur Respir J 2005; 26:1138–1180.
154. Woodhead M, et al. Guidelines for the management of adult lower respiratory tract infections- Full version Clin Microbiol Infect 2011; 17(Suppl. 6):E1–E59.
155. IDSA/ATS guidelines: Recommended empiric antibiotics for community acquired pneumonia in adults 2018
156. Patil SV et al, In Vitro Fractional Inhibitory Concentration (FIC) Study of Cefixime and Azithromycin Fixed Dose Combination (FDC) Against Respiratory Clinical Isolates. Journal of Clinical and Diagnostic Research 2015; 9(2):DC13-DC15.
157. Chandey M, et al. Comparative efficacy and safety of azithromycin monotherapy and azithromycin+ cefixime combination therapy in uncomplicated typhoid fever. Int J Advances in Med. 2016; 3(3):764-767.
158. Zmora N, et al., Open label comparative trial of mono versus dual antibiotic therapy for Typhoid Fever in adults. PLoS Neglected Tropical Diseases. 2018; 12(4):e0006380.
159. Dhar R. Pneumonia: Review of Guidelines. J Assoc Physicians India 2012; 60(Suppl): 25-28.
160. Upadhyay R, et al. API Recommendations for the Management of Typhoid Fever J Assoc Physicians India 2015; 63(11):77-96.
161. Lipsky BA, et al. Diagnosis and Treatment of Diabetic Foot Infections. Clinical Infectious Diseases 2004; 39: S104–S114.
162. Lipsky BA, et al. 2012 Infectious Diseases Society of America Clinical Practice Guideline Diagnosis and Treatment of Diabetic Foot Infections. Clinical Infectious Diseases 2012; 54(12):132–173.
163. Lipsky BA. Medical treatment of diabetic foot infections. Clin Infect Dis. 2004; 39:885-910.
164. Bader MS. Diabetic foot infection, Am Fam Physician. 2008;78(1):71-9.
165. Bonhoeffer S, et al. Evaluating treatment protocols to prevent antibiotic resistance. Proceedings of the National Academy of Sciences of the United States of America. 1997; 94(22): 12106-12111
166. Ahmed A, et al. Current concepts in combination antibiotic therapy for critically ill patients. Indian Journal of Critical Care Medicine, 2014; 18(5):310-314.
167. Plouffe JF. Importance of atypical pathogens of community-acquired pneumonia. Clin Infect Dis. 2000; 31(Suppl 2):S35-9.
168. Masterton RG, et al. Guidelines for the management of hospital-acquired pneumonia in the UK: report of the working party on hospital-acquired pneumonia of the British Society for Antimicrobial Chemotherapy, J Antimicrob Chemother 2008 ;62:5-34.
169. Petrosillo N, et al. Treatment options for community-acquired pneumonia in the elderly people. Expert Rev Anti Infect Ther 2015; 13(4):473-85.
170. Audimulapu S, et al. Clinico-microbiological profile of women with vaginal discharge. International Archives of Integrated Medicine 2017; 4(6):45-50.
171. Chaudhary V, et al. Clinico-microbiological profile of women with vaginal discharge in a tertiary care hospital of northern India. Int J Med Sci Public Health. 2012; 1(2): 75-80.
172. Schmidt H, et al. Microbiology of vaginal discharge in general practice, Scand J Prim Health Care. 1986; 4:75-80.
173. Barakoti A, et al. Microbiological Study of organisms causing abnormal vaginal discharge. Nepal Med Coll J 2017; 19(1):41-45.
174. Kore S, et al. Syndromic Management of Vaginal Discharge our Experience. Bombay Hospital Journal [Available at: http://www.bhj.org.in/journal/2004_4505_jan/html/syndromic_06.htm]
175. Jogi SR. Vaginal discharge: evaluation of syndromic management in Chhattisgarh Institute of Medical Sciences, Bilaspur, C.G. Int J Reprod Contracept Obstet Gynecol 2015; 4(5):1534-1538.
176. Sharma J, et al. A Prospective Study of Comparison of Efficacy of two combination treatment Regimens in syndromic Treatment of Pelvic Inflammatory Disease. The Internet Journal of Gynecology and Obstetrics 5(2): 1-5. [Available at: http://ispub.com/IJGO/5/2/3846#]
177. Gonococcal Infections in adolescents and adults, Sexually transmitted Diseases Guidelines, 2015. [Available at: https://www.cdc.gov/std/tg2015/gonorrhea.htm]
178. Zemouri C, et al. The Performance of the Vaginal DischargeSyndromic Management in Treating Vaginal and Cervical Infection: A Systematic Review and Meta-Analysis. A Systematic Review and Meta-Analysis. PLoS One 2016; 11(10) e0163365.
179. Federal Democratic Republic of Ethiopia Ministry of Health. National Guidelines for the Management of Sexually Transmitted Infections using Syndromic Approach, 2015, Pp 1-72.
180. Duff P, et al. Amoxicillin treatment of Bacterial Vaginosis during pregnancy. Obstet Gynecol; 1991; 77:431-435.
181. Centre for Disease Control and Prevention. Bacterial Vaginosis; Sexually Transmitted Diseases Treatment Guidelines, 2015. [Available at: https://www.cdc.gov/std/tg2015/bv.htm]
182. Jackson MA, et al. The Use of Systemic and Topical Fluoroquinolones, Pediatrics 2016; 138(5). pii:e20162706.
183. Koyle MA, et al. Pediatric Urinary Tract Infection: The role of fluoroquinolones. Pediatric Infectious Disease Journal 2003; 22:1133-37.
184. Islam N. On a national drug policy for Bangladesh. Tropical Doctor 1984; 14:327.
185. National Institute for Care and Health Excellence. Respiratory tract infections (self-limiting): prescribing antibiotics. Clinical Guideline [Available t: nice.org.uk/guidance/cg69]
186. National Institute for Care and Health Excellence. Sore throat (acute) anti-microbial prescribing. [Available at: https://www.nice.org.uk/guidance/ng84]
187. National Institute for Care and Health Excellence. Sinusitis (acute) anti-microbial prescribing. [Available at: https://www.nice.org.uk/guidance/ng79]

Dermatology

188. Verma SB. Topical corticosteroid misuse in India is harmful and out of control. BMJ 2015, 351: h6079 doi:10.1136/bmj.h6079
189. Verma SB. Sales, status, prescriptions and regulatory problems with topical steroids in India. Indian Journal of Dermatology Venereology and Leprology 2014; 80(3):201-3.
190. Verma S, et al. The Great Indian Epidemic of Superficial Dermatophytosis: An Appraisal. Indian Journal of Dermatology 2018; 62(3):227-236.
191. Brook I et al., Microbiology of infected atopic dermatitis, Int J Dermatol. 1996; 35(11):791-3.
192. Brook I. Secondary bacterial infections complicating skin lesions; J Med Microbiol 2002; 51(10):808-12.
193. Shroff HM. Evaluation of Efficacy, Safety and Tolerability of a Combination of Clobetasol, Neomycin and Miconazole Versus Betamethasone, Clotrimazole and Neomycin Versus Betamethasone, Gentamycin and Miconazole in Subjects with Eczematous Disorders Associated with underlying Tinea or Yeast Infections. Indian Medical Gazette 2014; 9:325-332
194. Barba-Rubio J, et al., Comparative merits of two topical corticosteroid antimicrobial drugs; J Int Med Res. 1981; 9(6):453-8.
195. Pratap DVS, et al. Evaluation of efficacy, safety, and tolerability of fixed dose combination (FDC) of halometasone 0.05% and fusidic acid 2% w/w topical cream versus FDC of betamethasone valerate 0.12% and neomycin sulphate 0.5% w/w topical cream in the treatment of infected eczematous dermatosis in Indian subjects: A randomized open-label comparative phase III multi-centric trial; Indian J Dermatol 2013; 58(2):117-123
196. Trimovate- Summary of product characteristics (SmPC)-(eMC) available at: https://www.medicines.org.uk/emc/product/9/smpc
197. Safeguarding public health. Clobetasol Propionate/neomycin sulphate/nystatin 0.5mg/5mg/100000IU/g cream PL17736/128. Clobetasol Propionate/neomycin sulphate/nystatin 0.5mg/5mg/100000IU/g ointment PL17736/0129. Available at: http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con222609.pdf
198. Rubel D, et al., Consensus guidelines for the management of atopic dermatitis: An Asia–Pacific perspective. Journal of Dermatology 2013; 40: 160-171.
199. Lewis-Jones S, et al., Management of atopic eczema in children aged up to 12 years: summary of NICE guidance. BMJ. 2007; 335(7632):1263–1264.
200. Darsow U et al. Position paper on diagnosis and treatment of atopic dermatitis; J Eur Acad Dermatol Venereol 2005; 19(3):286-95.
201. Marras F. Therapeutic usefulness of a corticosteroid, antibacterial and antifungal combination in skin diseases of various origins. Pharmatherapeutica 1985; 4(2):88-91.

202. Pazzaglia A, Therapeutic effects and tolerance of an extempore combination of an antibacterial, an anti-inflammatory and an antimycotic cream in skin diseases of various origins; Pharmatherapeutica 1985; 4(2):122-5.
203. Pellerano S. Use of a combination of an anti-inflammatory steroid, an antibacterial agent and an antifungal in dermatological practice; Int J Clin Pharmacol Ther Toxicol 1985; 23(4):215-8.
204. Haddican M, et al. Retapamulin 1% Ointment and Clobetasol Propionate 0.05% Foam is More Efficacious than Vehicle Ointment and Clobetasol 0.05% Propionate Foam in the Treatment of Hand/Foot Dermatitis. A single center randomized double-blind stud.. J Clin Aesthet Dermatol 2014; 7(7): 32–6.
205. Chari SV, et al., An Open, Comparative, Randomized, Parallel, Post Marketing, Multicentric Trial to Compare the Safety and Efficacy of Formula A (Ofloxacin + Ornidazole + Terbinafine Hydrochloride + Clobetasol Propionate) versus Formula B (Clotrimazole + Beclometasone Dipropionate + Neomycin Sulphate), Formula C (Clotrimazole + Beclometasone Dipropionate + Neomycin Sulphate) and Formula D (Clotrimazole + Beclometasone Dipropionate + Neomycin Sulphate) in the Treatment of Patients with Vaginitis. Indian Medical Gazette 2014; 288-296 [Available at: http://medind.nic.in/ice/t14/i8/icet14i8p288.pdf]
206. Franchi G. Treatment of dermatological conditions with a combination of an antibacterial agent an antifungal agent and an antiinflammatory steroid, Int J Clin Pharmacol Ther Toxicol 1985; 23(9):488-90.
207. Barba-Rubio J, et al. Comparative merits of two topical corticosteroid antimicrobial drugs; J Int Med Res. 1981; 9(6):453-8.
208. Faghihi G, et al. The efficacy of '0.05% Clobetasol + 2.5% zinc sulphate' cream vs. '0.05% Clobetasol alone' cream in the treatment of the chronic hand eczema: a double□blind study. JEADV 2008; 22:531-536.
209. Paller A, et al. An investigation into multifaceted mechanisms of action of allantoin in wound healing; J Am Acad Dermatol 2017; 76(6), Supplement 1 AB40.
210. Summary of product characteristics (SmPC)- Dermovate-NN Cream. Clobetasol Propionate/neomycin sulphate/nystatin 0.5mg/5mg/ 100000IU/g ointment.
211. eMC. Trimovate cream Summary of Product characteristics (smpc); Ennogen Healthcare Ltd. [Available at: https://www.medicines.org.uk/emc/product/8734/smpc]
212. Patient Information Leaflet Lotrisome; (clotrimazole and Betamethasone dipropionate) Cream and lotion. [Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/018827s049lbl.pdf]

ENT

213. Bolt P, et al. Topical lignocaine for pain relief in acute otitis media: results of a double-blind placebo-controlled randomised trial. Arch Dis Child 2007; 93:40- 44.
214. Agarwal P et al. Otomycosis in a Rural Community Attending a Tertiary Care Hospital, Assessment of Risk Factors and Identification of Fungal and Bacterial Agents. J Clin Diagn Res 2017;11(6):DC14-DC18.
215. Saki N et al., Prevalence of otomycosis in Khouzestan Province, south-west Iran. The Journal of Laryngology & Otology, 2012, 25-27.
216. Davies S, et al. Ear drops containing steroids were better than acetic acid for otitis externa. Evid Based Nurs 2004;7(2):43
217. Rosenfeld RM, et al. Clinical Practice Guideline: Acute Otitis Externa. Otolaryngology–Head and Neck Surgery 2014; 150(1S):S1-S24.
218. Mosges R, et al., A meta-analysis of the efficacy of quinolone containing otics in comparison to antibiotic–steroid combination drugs in the local treatment of otitis externa, Current Medical Research and Opinion 2011;27(10): 2053–2060.
219. Kaushik V, et al. Interventions for acute otitis externa (Review). Cochrane Database of Systematic Reviews 2010; Issue 1. Art. No.: CD004740.
220. Wai TKH, et al. A benefit-risk assessment of ofloxacin otic solution in ear infection. Drug Saf 2003; 26(6):405-20.
221. Canesten solution-Summary of Product Charecteristics (SmPC)-(eMC). Available at: https://www.medicines.org.uk/emc/product/2209/smpc
222. Magomedov MM, et al., Comparative characteristics of the local application of anti-inflammatory drugs for otitis externa and otitis media. Vestn Otorinolaringol 2012;5:69-72.
223. Lorente J et al. Ciprofloxacin plus Fluocinolone acetonide versus Ciprofloxacin alone in the treatment of diffuse otitis externa; J Laryngol Otol. 2014;128(7):591-8.
224. Prasad SC, et al. Primary Otomycosis in the Indian Subcontinent: Predisposing Factors, Microbiology, and Classification; International Journal of Microbiology 2014; Article ID 636493, http://dx.doi.org/10.1155/2014/636493.
225. Yaniv E, et al. Comparative efficacy of two anti-bacterial/anti-inflammatory formulations (Auricularum otic powder and Dex-Otic drops) in the medical treatment of otitis externa; Curr Med Res Opin 2002;18(8):520-2.
226. Enoz M, et al. Bacterial and fungal organisms in otitis externa patients without fungal infection risk factors in Erzurum, Turkey. Braz J Otorhinolaryngol 2009;75(5):721-5.
227. Mgbe R, et al. Otomycosis- A Management Challenge In Calabar, South-South Nigeria. The Internet Journal of Third World Medicine. 2010; 9(2) [Available at: http:// http://ispub.com/ijtwm/9/2/7830]
228. Kiran MM, et al., Safety and efficacy of a topical combination of Ofloxacin, Clotrimazole, Beclomethasone and Lignocaine for management of mixed ear infections: Phase IV study; IJMSIR, 2017; 2(3):42-49.
229. Shokohi T, et al., Bacteriological and Mycological study of external otitis in-patients referred to ENT clinic of Boo Ali Sina Hospital in Sari in summer 1999; J Mazandaran Univ Med Sci 2001; 11(32): 1-11.
230. Philip A, et al. Effectiveness of 7.5 Percent Povidone Iodine in Comparison to 1 Percent Clotrimazole with Lignocaine in the Treatment of Otomycosis. ISRN otolaryngology 2013; Article ID: 239730
231. Mustafa M, et al. Acute Otitis Externa: Pathophysiology, Clinical presentation, and Treatment; IOSR Journal of Dental and Medical Sciences 2015; 14(7):73-78.
232. Bak JP, et al. Treatment of otitis externa with miconazole nitrate. A comparative study involving 85 cases. S Afr Med J. 1983; 63:562-3.
233. Roland PS, et al. Microbiology of acute otitis externa, The Laryngoscope. 2002; 112:1166-77.
234. Kaushik V et al., Cochrane Database of Systematic Reviews, Issue 1, 1-118. Art. No.: CD004740
235. Sander R, et al. Otitis Externa: A Practical Guide to Treatment and Prevention. American Family Physician, 2001, 63, 927-936.
236. Hui CPS. Acute otitis externa. Paediatric Child Health 2013; 18(2):96-98.
237. Licberthal AS. The Diagnosis and Management of Acute Otitis Media. Pediatrics 2013; 131(3): [Available at: http://pediatrics.aappublications.org/content/early/2013/02/20/peds.2012-3488]
238. Foxlee R, et al. Topical analgesia for acute otitis media (Review). The Cochrane Library 2007; Issue 2, Pp 1-19
239. Prajapati K, et al. Critical Analysis of Cardiovascular and Central Nervous System Fixed Dose Combinations Available in Indian Market. J Clinical and Diagnostic Research 2016; 10(12):FC36-FC39
240. Rosenson RS, et al. An assessment by the Statin Muscle Safety Task Force: 2014 Update. Journal of Clinical Lipidology 2014; 8:S58-S71
241. Bhagat S, et al. Serratiopeptidase: A systematic review of existing evidence. International Journal of Surgery 2013; 11:209-217

Gastroenterology

242. Bachmann KA, et al. Drug Interactions of H_2-Receptor Antagonists, Scand J Gastroenterol 1994; 29 (Suppl 206):14-19.
243. Darish-Damavandi M, et al. A systematic review of efficacy and tolerability of Mebeverine in irritable bowel syndrome, World Journal of Gastroenterology 2010;16 (5):547-553.
244. Pro-Banthine Tablets-Summary of Product Charecteristics (SmPC)-(eMC) [Available at https://www.medicines.org.uk/emc/product/229]
245. Selvi T, et al. Helicobacter pylori infection in India from a western perspective. Indian J Med Res. 2012; 136: 549-562.
246. Galeazzi RL. The effect of an antacid on the bioavailability of indomethacin. European Journal of Clinical Pharmacology 1977; 12(1):65-8
247. Chandler SG, et al. Fixed dose drug combinations (FDC's): Rational or irrational: a view point. British Journal of Clinical Pharmacology 2007; 65(5):795-796.
248. Chey WD, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. Am J Gastroenterology 2017;112: 212-238.
249. Jain NK, et al. Rationality of Fixed Dose Combinations: An Indian S scenario. The Pharma Research 2009;01:158-168.
250. Laaveri T, et al. Systematic review of loperamide: No proof of antibiotics being superior to loperamide in treatment of mild/moderate travellers' diarrhoea. Travel Medicine and Infectious Disease 2016; 14:299-312.
251. Foody JM. Amoxicillin is Ineffective for Bacterial Vaginosis During Pregnancy. Obstet Gynecol 1991; [Available at https://www.jwatch.org/jw199103260000004/1991/03/26/amoxicillin-ineffective-bacterial-vaginosis]
252. Nigam MP, et al. Fixed dose combinations- to prescribe or not to prescribe: a dilemma of medical profession. Int J Basic Clin Pharmacol 2013; 3(1):105-113.
253. Shahid SK, Fixed Drug Combination for Treatment of Diarrhea. Indian Pediatrics 1998; 35: 941-942.
254. Kasaria R, et al. Irrational Drug Combinations. International Journal of Experimental Pharmacology 2013;3(2): 52-56.
255. Sheth SG, et al. Toxic megacolon-Up to date 2013. [Available at https://www.uptodate.com/contents/toxic-megacolon]

256. Singh P et al. Rational Use of Medicine: A Pressing Need, J Rational Pharmacother Res 2013; 1 (1):10-14.
257. Uribe M, et al. Decreased Bioavailability of Prednisone Due to Antacids in Patients with Chronic Active Liver Disease and in Healthy Volunteers. Gastroenterology 1981; 80:661-5.
258. Patient Information Leaflet – Flagyl® - Metronidazole Tablets [Available at http://labeling.pfizer.com/ShowLabeling.aspx?id=570]
259. Yazdanpanah K, et al. Efficacy of Zinc Sulfate in Peptic Ulcer Disease: A Randomized Double-Blind Clinical Trial Study. Journal of Clinical and Diagnostic Research 2016; 10(8):OC11-OC15.
260. Yewale VN, et al. Promoting Appropriate Use of Drugs in Children. International Journal of Paediatrics 2012; Article ID 906570.
261. Thirunavukkarasu AB, et al. Nitazoxanide use in Rota Viral Diarrhea. Cure or Controversy? Indian J Pediatr 2010; 77:1450.
262. Hemphill A, et al. Nitazoxanide, a broad-spectrum thiazolide anti-infective agent for the treatment of gastrointestinal infections. Expert Opin. Pharmacother 2006; 7(7): 953-964.
263. Anderson VR, et al. Nitazoxanide A Review of its Use in the Treatment of Gastrointestinal Infections. Drugs 2007;67(13): 1947-1967.
264. Mahapatro S et al. Nitazoxanide in Acute Rotavirus Diarrhea: A Randomized Control Trial from a Developing Country. Journal of Tropical Medicine 2017; Article ID: 7942515.
265. De Francesco V, et al. First-line therapies for Helicobacter pylori eradication: a critical reappraisal of updated guidelines. Annals of Gastroenterology 2017;30: 373-379.
266. Mero WMS, et al. Microorganisms and viruses causing diarrhea in infants and primary school children and their relation with age and sex in Zakho city, Kurdistan Region, Iraq. International Journal of Research in Medical Sciences 2015; 3(11): 3266-3273. .
267. Shrivastava AK, et al. Multiple etiologies of infectious diarrhea and concurrent infections in a pediatric outpatient based screening study in Odisha, India. Gut Pathog 2017; 9:16
268. Dalrymple J, et al. Diagnosis and management of irritable bowel syndrome in adults in primary care: summary of NICE guidance. BMJ 2008; 336: 556-8.
269. Fukudo S, et al. Evidence-based clinical practice guidelines for irritable bowel syndrome. J Gastroenterology 2014; [DOI 10.1007/s00535-014-1017-0]
270. Ford AC, et al. American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. The American Journal of Gastroenterology, 2014;109: S2-S26.
271. Proton Pump inhibitors, Bulletin, All wales therapeutics and Toxicology Centre, WeMeReC Bulletin 2016. [Available at: https://www.wemerec.org/Documents/Bulletins/PPIBulletinOnline.pdf]
272. Shaman R, et al. Functional abdominal pain disorders in children. Expert Rev Gastroenterology and Hepatology 2018; 12(4):369-390.
273. Goldman JA, et al. 18th Expert Committee on the selection and use of essential medicines (2011) Fluoroquinolone use in Paediatrics: Focus on safety and Place in Therapy. World Health Organization, 30-31 March 2010, Geneva, Switzerland. [Available at: http://www.who.int/selection_medicines/committees/expert/18/applications/fluoroquinolone_review.pdf?ua=1]
274. Fox LM, et al. Nitazoxanide: a new thiazolide antiparasitic agent. Clin Infect Dis. 2005; 40: 1173-80.
275. European Association for the Study of the Liver (EASL). EASL Clinical Practice Guidelines on the prevention, diagnosis and treatment of gallstones. Journal of Hepatology 2016; 65:146-181.
276. Powell RJ, et al. BSACI guideline for the management of chronic urticarial and angioedema. Clinical and Experimental Allergy 2015; 45:547-566.
277. Editorial. WHO Pharmaceuticals Newsletter No. 4, 2002; Pp 1-15 [Available at: http://apps.who.int/iris/bitstream/handle/10665/255812/WPN-2002-04-eng.pdf?sequence=1&isAllowed=y]
278. Xue XC, et al. Randomized controlled study of efficacy and safety of drotaverine hydrochloride in patients with irritable bowel syndrome. Medicine 2017; 96:51(e9235)
279. Chi CY, et al. Epidemiology, clinical features, and microbiology of patients with diarrhea in community clinics in Taiwan. Journal of Microbiology, Immunology and Infection 2017; 1-8. [Available at: https://reader.elsevier.com/reader/sd/2372822F0FE0E40AFA284748F6AB7C9EDB9634240078B6BB2D57ADB9912F698D311FFBFE10B9746664DC936F7EA52ACC]
280. Rai RR, et al. Efficacy and Safety of Drotaverine Hydrochloride in Irritable Bowel Syndrome: A Randomized Double-Blind Placebo-Controlled Study. Saudi J Gastroenterol 2014; 20(6):378–382.
281. European Association for the Study of the Liver (EASL). EASL Clinical Practice Guidelines: The diagnosis and management of patients with primary biliary cholangitis. Journal of Hepatology 2017; 67:145-172.
282. Narang M, et al. Efficacy and safety of drotaverine hydrochloride in children with recurrent abdominal pain: A randomized placebo controlled trial. Indian Pediatrics 2015; 52(10):847–851.
283. Georgiadis GT, et al. Prokinetic agents: current aspects with focus on cisapride. Ann Gastroenterology 2000; 13(4):269-89

Neurology

284. Sokolova L, et al. Treatment of Vertigo: A Randomized, Double-Blind Trial Comparing Efficacy and Safety of Ginkgo biloba Extract, EGb 761 and Betahistine. International Journal of Otolaryngology 2014; 2014 [Article ID: 682439] Available at: http://dx.doi.org/10.1155/2014/682439.
285. Oosterveld WJ. Betahistine dihydrochloride in the treatment of vertigo of peripheral vestibular origin A double-blind placebo-controlled study. The Journal of Laryngology and Otology, 1984; 98: 37-41
286. Waegemans T, et al. Clinical Efficacy of Piracetam in Cognitive Impairment: A Meta-Analysis Dement Geriatr Cogn Disord 2002; 13:217–224
287. Szatmári S et al. Vinpocetine for cognitive impairment and dementia (Review); Cochrane Database of Systematic Reviews 2003; Issue 1. Art. No.: CD003119.
288. Okiyama M, et al. Drug Interactions between Imipramine and Benzodiazepines in Rats. Journal of Pharmaceutical Sciences 1988; 77(1): 56-63.
289. Feet PO, et al. A double blind study in out-patients with primary non-agitated depression treated with imipramine in combination with placebo, diazepam or dixyrazine Acta psychiatr scand. 1985; 72:334-340.
290. Toes MJ, et al. Drug Interactions with Paracetamol. American Journal of Therapeutics 2005; 12: 56–66.
291. Virtanen T, et al. Dyspepsia and constipation in patients with schizophrenia spectrum disorders. Nordic Journal of Psychiatry 2016; [Available at: http://dx.doi.org/10.1080/08039488.2016.1217044]
292. National Institute for Health and Care Excellence (NICE). Migraine prophylaxis: flunarizine; 2014. Available at: nice.org.uk/guidance/esuom33
293. Silberstein, SD, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology 2012; 78: 1337–1345.
294. Lipton RB, et al. Caffeine in the management of patients with headache. The Journal of Headache and Pain 2017: 18, 107.
295. Jovel CAE, et al. Caffeine and headache: specific remarks. Neurologia 2017; 32(6):394-398.
296. Lee MJ, et al. Caffeine discontinuation improves acute migraine treatment: a prospective clinic based Study. The Journal of Headache and Pain 2016; 17:71.
297. Derry S et al. Paracetamol (acetaminophen) with or without an antiemetic for acute migraine headaches in adults (Review); Cochrane Database of Systematic Reviews 2013; Issue 4. Art. No.: CD008040.
298. Starke PR, et al. Boxed warning added to Promethazine labeling for pediatric use. N Engl J Med 2005; 352(25):2653.
299. Solanki MS, et al. Irrational fixed dose combinations of psychotropic drugs in India: Cause of concern. Indian J Pharmacol 2016;48(4):468-9
300. Shelton RD, et al. Assessing the effects of L-methylfolate in Depression Management: Results of a Real-World Patient Experience Trial. The Primary Care Companion for CNS Disorders 2013; 15:4 PCC.13m01520
301. Bansal RK, et al. Role of adjunctive L-methylfolate with selective serotonin reuptake inhibitor in depressed patients at a tertiary care centre. International Journal of Medical Research Professionals 2016; [DOI: 10.21276/IJMRP.2016.2.4.004]

Pulmonary Medicine

302. Taskar, VS, et al. Effect of Bromhexine on sputum Amoxycillin levels in lower respiratory infections. Respiratory Medicine 1992; 86:157-160.
303. Zanasi A, et al. A reappraisal of the mucoactive activity and clinical efficacy of Bromhexine. Multidisciplinary Respiratory Medicine 2017; 12:7, 1-14.

304. US Food and Drug Administration. FDA Drug Safety Communication: FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18years and older, 2017, 1-3 [Available at: https://www.fda.gov/Drugs/DrugSafety/ ucm590435. htm.]
305. Snidvongs K, et al. Sedative Effects of Levocetirizine: A Systematic Review and Meta-
306. Analysis of Randomized Controlled Studies. Drugs 2017: 77(2):175-186.
307. Hemila H, et al., Zinc lozenges and the common cold: a meta-analysis comparing zinc acetate and zinc gluconate, and the role of zinc dosage. Journal of the Royal Society of Medicine Open 2017; 8(5), 1-7
308. Shah S, et al., Critical analysis of antimicrobial and respiratory fixed dose combinations available in Indian market. International Journal of Medicine and Public Health, 2015; 5(2):161-164.
309. Eccles R., et al. Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases 2014; 4:73-82.
310. European Medicines Agency. Revised Assessment Report 2015. EMA/PRAC/800767/2015 Pharmacovigilance Risk Assessment Committee (PRAC), Ambroxol and Bromhexine containing medicinal products, 2015. [Available at: http://www.ema.europa.eu/ docs/en_GB/document_library/Referrals_document/Ambroxol_and_bromhexine_31/Recommendation_provided_by_Pharmacovigilance_ Risk_Assessment_Committee/WC500184106.pdf
311. World Health Organization. Anti-allergics and Medicines used in Anaphylaxis. Available at: http://archives.who.int/eml/ expcom/children/Reviewers/3_rev1.pdf
312. Simens FER, et al. H1 Antihistamines Current Status and Future Directions. World Allergy Open Journal 2008; 1(9):145-155.
313. Salm-Reifferscheidt L et al. Tramadol: Africa's opioid crisis, The Lancet 2018: 391:1982-3.
314. Deckx L, et al., Nasal decongestants in monotherapy for the common cold (Review). Cochrane Database of Systematic Reviews 2016; 10: 1-87.
315. De Sutter AI, et al. Oral antihistamine-decongestant-analgesic combinations for the common cold (Review). Cochrane Database of Systematic Reviews 2012; 2:1-100.
316. Zanasi A, et al. Levodropropizine for treating cough in adult and children: a meta-analysis of published studies. Multidisciplinary Respiratory Medicine 2015; 10:19.
317. Gupta PR, et al. Ambroxol- Resurgence of an old molecule as an anti-inflammatory agent in chronic obstructive airway diseases. Lung India 2010; 27(2); 46-48.
318. Roy V, et al. Fixed-dose combinations for cough and common cold in India: an assessment of availability and rationality. Fundamental and Clinical Pharmacology 2011; 25:258-266.
319. Matysiak K, et al. Calcium preparations do not inhibit allergic reactions: a randomized controlled trial. Pol Arch Intern Med 2017; 127(9):582-8.
320. Findlay JWA. Review Articles. Pholcodine, Journal of Clinical Pharmacy and Therapeutics 1988; 13: 5-17.
321. Fashner J, et al., Treatment of the Common Cold in Children and Adults. American Family Physicians 2012; 86:153-159.
322. Department of Health and Aging. Therapeutic Goods Administration, Review of cough and cold medicines in children Tabulated summaries of clinical trials prepared by the TGA to accompany the Report by the External Reviewers, 2009. [Available at: https://www.tga.gov.au/sites/default/files/consult-labelling-cough-cold-091022-summary-ct.pdf
323. Simasek M, et al. Treatment of the Common Cold. American Family Physicians 2007; 75;515-20
324. Rogers DF. Mucoactive drugs for asthma and COPD: any place in therapy? Expert Opin. Investig. Drugs 2002; 11(1):15-35.
325. Picon PD, et al. Symptomatic treatment of the common cold with a fixed-dose combination of Paracetamol, Chlorphenamine and Phenylephrine: a randomized, placebo-controlled trial, BMC Infectious Diseases 2013; 13:556.
326. Malek J. Treating coughs and cold, inPHARMation 2015: 16(4). [Available at: https://www.psa.org.au/download/self-care/4614%20May%20inPHARMation%202015_web.pdf
327. Sung V, et al. Cough and cold remedies for children. Australian prescriber 2009; 32:122-124.
328. Allan GM, et al. Prevention and treatment of the common cold: making sense of the evidence. CMAJ 2014; 186(3): 190-199.
329. Global initiative for chronic obstructive lung disease, Global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease, 2018, 1-123.
330. National Institute for Health and Care Excellence (NICE). Common cold. Last revised in August 2016 [Available at: https://cks.nice.org.uk/common-cold]
331. MHRA. Over the counter cough and cold medicines for children, 2009. [Available at: https://www.gov.uk/drug-safety-update/over-the-counter-cough-and-cold-medicines-for-children,
332. Boots Pharmaceuticals Cold & Flu Relief Capsules (Caffeine, Paracetamol, Phenylephrine Hydrochloride) [Available at: https://www.medicines.org.uk/emc/files/pil.8283.pdf]
333. Taverner D, et al. Nasal decongestants for the common cold (Review), The Cochrane Library, 2007; Issue 1:1-16.
334. Poole P, et al. Mucolytic agents versus placebo for chronic bronchitis or chronic obstructive pulmonary disease (Review), Cochrane Database of Systematic Reviews 2015; Issue 7: 1-96.
335. De Sutter AI. Antihistamines for the common cold (Review). Cochrane Database of Systematic Reviews 2015; Issue 11:1-102.
336. Agliati G. Effects of a Short Course of Treatment with Acebrophylline on the Mucus Rheological Characteristics and Respiratory Function Parameters in Patients Suffering from Chronic Obstructive Pulmonary Disease, The Journal of International Medical Research 1996; 24:302-310.
337. Birring SS, et al. Study: a real-world evaluation of an over-the-counter medicine in acute cough (a multicentre, randomised, controlled study). BMJ 2017; (7):e014112.
338. Eccles R, et al. Treatment of acute cough due to the common cold: multi-component, multi-symptom therapy is preferable to single-component, single-symptom therapy - a pro/con debate, Lung 2015; 194(1):15-20.
339. Singh M, et al. Zinc for the common cold (Review). The Cochrane Library 2013; Issue 6: 1-90.
340. Products authorised for use in children up to 6 years of age which can be sold as before. [Available at: http://news.bbc.co.uk/2/shared/ bsp/hi/ pdfs/27_03_08medicine.pdf]
341. GlaxoSmithKline. The Effect of Paracetamol, Pseudoephedrine Hydrochloride, Dextromethorphan Hydrobromide and Chlorpheniramine Maleate Tablets Compared to Placebo in Subjects Suffering From the Common Cold or Influenza, ClinicalTrials.gov. [Available at: https://clinicaltrials.gov/ct2/show/NCT02246166]
342. Fan Y, et al. An Overview of the Pediatric Medications for the Symptomatic Treatment of Allergic Rhinitis, Cough and Cold. Journal of Pharmaceutical Sciences 2013; 102:4213–4229.
343. Malesker MA, et al. Pharmacologic and Non pharmacologic Treatment for Acute Cough Associated with the Common Cold: CHEST Expert Panel Report. Chest 2017; 152(5):1021-1037.
344. Arroll B. Non-antibiotic treatments for upper-respiratory tract infections (common cold) Respiratory Medicine 2005; 99:1477–1484.
345. World Health Organization. Department of Child and Adolescent Health and Development, 2001. WHO cough and cold remedies for the treatment of acute respiratory infections in young children. Geneva, World Health Organization. WHO Reference No. WHO/FCH/CAH/01.02 [Available at: http://www.who.int/maternal_child_adolescent/documents/fch_cah_01_02/en/ and at http://apps.who.int/iris/handle/10665/66856]
346. Pozzi E. Acebrophylline: an airway mucoregulator and anti-inflammatory agent. Monaldi Arch Chest Dis 2007; 67(2): 106-115.
347. Morice AH, et al. Cough Guideline Group Recommendations for the management of cough in adults. Thorax 2006, 61(Suppl I), i1–i24.
348. Shields MD, et al. Cough Guideline Group Recommendations for the assessment and management of cough in children. Thorax 2008; 63(Suppl III): iii1–iii15.
349. National institute for Health and Care Excellence (NICE). Bronchiolitis in children: diagnosis and Management, NICE guideline 2015 [Available at: nice.org.uk/guidance/ng9]
350. National institute for Health and Care Excellence (NICE). Chronic obstructive pulmonary disease in Adults NICE 2011. [Available at: nice.org.uk/guidance/qs10 Quality Standard]
351. National institute for Health and Care Excellence (NICE). Chronic obstructive pulmonary disease in over 16s: diagnosis and management, NICE 2010, nice.org.uk/guidance/cg101
352. Pratter MR, et al. Cough and the Common Cold. ACCP Evidence-Based Clinical Practice Guidelines. CHEST 2006; 129:72s-74s.
353. Morice A, et al. Comprehensive evidence-based review on European antitussives. BMJ Open Resp Res 2016; 3:e000137.
354. USFDA drug safety labeling changes (SLC), Phenergan VC w/ codeine (NDA008306) (codeine phosphate, Phenylephrine hydrochloride and Promethazine hydrochloride), 2017 [Available at: https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/ index.cfm?event=searchdetail.page&DrugNameID=783

355. Science M, et al. Zinc for the treatment of the common cold: a systematic review and meta-analysis of randomized controlled trials. CMAJ 2012, 184(10):E551-E561
356. US Food and Drug Administration. CFR Code of Federal Regulation. Title 21. Subpart B: Active ingredients [Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=341&showFR=1&subpartNode=21:5.0.1.1.19.2
357. US Food and Drug Administration. CFR Code of Federal Regulation. Title 21. Subpart C: labeling [Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=341&showFR=1&subpartNode=21:5.0.1.1.19.3
358. Irvin RS. Assessing Cough Severity and Efficacy of Therapy in Clinical Research ACCP Evidence-Based Clinical Practice Guidelines. Chest 2006; 129: 232S–237S.
359. Bolser DC, et al. Cough Suppressant and Pharmacologic Protussive Therapy ACCP Evidence-Based Clinical Practice Guidelines. Chest 2006; 129:238S–249S.
360. Committee for the third edition of the COPD Guidelines of The Japanese Respiratory Society. Guidelines for the diagnosis and treatment of COPD (chronic obstructive pulmonary disease), Pocket Guide. The Japanese Respiratory Society 2010, 3rd edition. [Available at: http://www.jrs.or.jp/uploads/uploads/files/photos/765.pdf]
361. Malerba, M et al. Ambroxol in the 21st century: pharmacological and clinical update. Expert Opin Drug Metab Toxicol 2008; 4(8):1119-1129.
362. Eccles R. Substitution of Phenylephrine for Pseudoephedrine as a nasal decongeststant. An illogical way to control Methamphetamine abuse. Br J Clin Pharmacology 2006; 63(1):10-14.
363. Barnes PJ. Theophylline. American Journal of respiratory and critical care medicine 2013; 188:901-906.
364. Hatton RC, et al. Efficacy and Safety of Oral Phenylephrine: Systematic Review and Meta-Analysis. The Annals of Pharmacotherapy 2007; 41:381-390.
365. Weinberger M et al. Non prescription medications for respiratory symptoms: Facts and marketing fictions. Allergy Asthma Proc 2018; 39:169–176.
366. Rumore MM, Clinical pharmacokinetics of Chlorpheniramine. Drug Intelligence and Clinical Pharmacy 1984; 18:701-707.
367. De Sutter A. There is no good evidence for the effectiveness of commonly used over-the-counter medicine to alleviate acute cough. Evidence Based Medicine 2015; 20(3):98.
368. Kollar C, et al. Meta-Analysis of the Efficacy of a Single Dose of Phenylephrine 10 mg Compared with Placebo in Adults with Acute Nasal Congestion Due to the Common Cold. Clinical Therapeutics 2007; 29:1057-1070.
369. Chung KF et al. Chronic Cough Prevalence, pathogenesis, and causes of chronic cough. Lancet 2008; 371:1364–1374.
370. Padma L. Current Drugs for the Treatment of Dry Cough. J Assoc Physicians India 2013; 61(suppl):9-13.
371. Smith A, et al. Caffeine and the common cold. Journal of Psychopharmacology 1997; 11(4):319-324.
372. Meltzer EO, et al. Oral Phenylephrine HCl for Nasal Congestion in Seasonal Allergic Rhinitis: A Randomized, Open-label, Placebo controlled Study. J Allergy Clin Immunol Pract 2015; 3(5):702-8
373. Tietze K. Update: Safety and efficacy of oral Phenylephrine still in question. Pharmacy Today 2016, 14.
374. Rubin A, et al. A Double-Blind Randomized Study of an Aspirin/Caffeine Combination Versus Acetaminophen/Aspirin Combination Versus Acetaminophen Versus Placebo in Patients with Moderate to Severe Post-Partum Pain. J Int Med Res 1984; 12:338-345.
375. Iqbal N, et al. The effect of Caffeine on the pharmacokinetics of Acetaminophen in man, biopharmaceutics and drug disposition. 1995; 16:481-487.
376. Pappas DE. The common cold in children: Management and prevention. UpToDate
377. Sexton DJ, et al. The common cold in adults: Treatment and prevention UpToDate.
378. Ministry of Public Health, Government of Qatar. Clinical Guidelines for the State of Qatar; The diagnosis and management of the common cold in adults and children: ministry of public health Doha, Qatar, 2016 [Available at: https://www.moph.gov.qa/health-strategies/Documents/Guidelines/MOPH%20Guideline%20-%20Common%20Cold%20v1-1%20FINAL.pdf]
379. Medicines and Healthcare Product Regulatory Agency (MHRA). Lemsip Max Day & Night Cold & Flu Relief Capsules (paracetamol, caffeine and phenylephrine hydrochloride) PL 00063/0529UKPAR, 2015, 1-18. [Available at: http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con062552.pdf]
380. Horak. F, et al. Efficacy and safety relative to placebo of an oral formulation of Cetirizine and sustained- release Pseudoephedrine in the management of nasal congestion. Allergy1998; 53:849-56
381. US Food and Drug Administration. FDA Drug Safety Communication: FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. [Available at: https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm]
382. Sing R. Rationality of fixed dose combination for the management of upper respiratory tract infection. Research Journal of Pharmaceutical, Biological and Chemical Science 2017; 8(4):427-434.
383. Cooper RJ. Over the counter abuse– a review of the literature. Journal of substance use, 2013; 18(2):82-107.
384. EMC patient info leaflet. PIL Pholcodine Linctus BP. Available at: https://www.medicines.org.uk/emc/files/pil.4598.pdf]
385. UCB Pharma Product Information: Zyrtec (Cetirizine hydrochloride). [Available at: https://gp2u.com.au/static/pdf/Z/ZYRTEC-PL.pdf]
386. Highlights of Prescribing Information. XYZAL (Levocetirizine dihydrochloride) [Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022064s009lbl.pdf]
387. Medicines and Healthcare Product Regulatory Agency. MHRA- Dextromethorphan Hydrobromide 10mg/5ml oral solution PL 17907/0314 [Available at: http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con146863.pdf]
388. De Blasio F, et al. Cough management: a practical approach. Cough. 2011; 7:7.
389. Lowry JA, et al. over the counter medications: update on cough and cold preparation. Pediatr Rev 2015; 36(7):286-97.
390. Prescribing Information; APO-LORATIDINE (Loratidine Tablets) 10 mg. [Available at: https://www.apotex.com/ca/en/products/downloads/di/0117_PIL.pdf]
391. Hatton RC. Over the counter oral phenylephrine: A placebo for Nasal congestion. J Allergy Clin Immunol Pract 2015; 3:709-10.
392. Nagaraju B, et al. A study to evaluate the effect of dosing time of deriphyllin retard as bronchodilator in asthma patients. Journal of Pharmaceutical and Biological Sciences [Available at: Journal of Pharmaceutical and Biological Sciences]

Gynecology and Urology

393. Senok AC et al. Probiotics for the treatment of bacterial Vaginosis. Cochrane Database Systematic Review 2009; Issue 4:CD006289
394. Kalapai G, et al. Systematic review of tranexamic acid adverse reactions. Journal of Pharmacovigilance 2015; 3(4). [Available at: https://www.omicsonline.org/open-access/systematic-review-of-tranexamic-acid-adverse-reactions-2329-6887-1000171.php?aid=58640]
395. Centers for Disease Control and Prevention. Bacterial vaginosis. [Available at: https://www.cdc.gov/std/tg2015/bv.htm]

6 Appendix

F. No- 18-04/2018-DC
Directorate General of Health Services
Office of Drugs Controller General (India)
(DCC/DTAB Division)

Date: 19 FEB 2018

NOTICE

Subject: Consideration of the directions of the Hon'ble Supreme Court of India in the case of 344 FDCs + 05 FDCs prohibited vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855(E) dated 08.06.2017 and constitution of a sub-committee for having a relook in these cases- Regarding.

In the 78th meeting of the Drugs Technical Advisory Board (DTAB) held on 12th February, 2018 under the Chairmanship of the Director General of Health Services deliberated the directions of the Hon'ble Supreme Court of India dated 15.12.2017 in regard to the notifications issued by the Govt. of India prohibiting 344 FDCs +05 FDCs vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855(E) dated 08.06.2017 respectively.

The Hon'ble Supreme Court in its order dated 15.12.2017 had directed that these cases should go to the DTAB and/or its sub-committee formed by the DTAB for the purpose of having a relook into these cases. The committee will not only hear the petitioners/appellants before but they also hear submissions from all India Drugs Action Network. The DTAB/sub-committee set up for the purpose will deliberate on the parameters set out in section 26A of the Drugs & Cosmetics Act.

Accordingly, a sub-committee was constituted under the Chairmanship of Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, ICMR, Mumbai, to examine the banned 344 FDCs + 5 FDCs vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855(E) dated 08.06.2017 respectively.

This is for the information of all stakeholders.

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:

1. Drugs Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE
2. IT Division, CDSCO to update the website for information to all stakeholders.

617

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 1st March 2018 for examination of cases of banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. NilimaKshirsagar, The Chair in Clinical Pharmacology, ICMR, Mumbai; (Chairperson).
2. Dr. Rao V. S. V. Vadlamudi, President, Indian Pharmaceutical Association, Telangana. (Member).
3. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
4. Dr. R. N. Tandon, Honorary Secretary General, Indian Medical Association, New Delhi (Member).
5. Dr. Agam Vora, Org. Secretary, Indian Medical Association, Mumbai (Member).
6. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
7. Dr. Sandeep B. Bavdekar, Former Prof. Head Pediatrics T. N. Medical College BYL Nair Hospital, Mumbai (Co-opted Member).
8. Shri. Sanjeev Kumar, Deputy Drugs Controller (India), CDSCO (HQ), New Delhi; (Convener).

The Convener welcomed the members of DTAB Sub-Committee for its first meeting for examination of cases of banning of 344 FDCs + 05 FDCs and apprised the Committee members about the background with respect to 344+ 5 FDCs.

The Committee was also apprised about the terms of references based on Hon'ble Supreme Court Judgement dated 15.12.2017.

The Chairperson, thanked all the expert members for attending the meeting at such a short notice. She mentioned that as per Hon'ble Supreme Court, this Committee has been assigned the task to examine 344 + 5 FDCs.

After detailed deliberations, the DTAB Sub-Committee finalised the following:

1. Format for submission of information by appellant/petitioner/manufacturer/ marketing company on FDC to DTAB Sub-Committee (Annexure A)
2. Format for Subject Expert Committee (FDC) Report (Annexure B)
3. Panel of Subject Experts (Annexure C)
4. Format for submission of information on FDC to DTAB Sub-Committee by the All India Drug Action Network, AIDAN (Annexure D)

618

The Committee requested the Convener to provide to the appellants/ petitioners, the format for submission of information on FDC to DTAB Sub-Committee, preferably by 15th March 2018. It authorized the Convener to work out the modalities e.g. putting the announcement and formats on the website and sending e-mails/ letters. The appellants/ petitioners/ concerned manufacturers should be given 3 weeks' time to reply (from the date of issuance of letter) i.e. by 7th April 2018 till 6.00 PM.

The Convener with his staff will compile the information received by 19th April 2018. The next DTAB Sub-Committee meeting will be held tentatively on 20th April 2018 for reviewing the applications received and discussing the further modalities viz. calendar for Subject Expert Committee meetings, hearing of the appellants/ petitioners/ concerned manufacturers and AIDAN.

Meeting of Sub-Committee ended with vote of thanks to Chairperson.

Minutes of the 2nd Meeting of Sub-Committee of Drug Technical Advisory Board held on 20th April 2018 for examination of cases of banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, ICMR, Mumbai; (Chairperson).
2. Dr. Rao V. S. V. Vadlamudi, President, Indian Pharmaceutical Association, Telangana. (Member).
3. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
4. Dr. R. N. Tandon, Honorary Secretary General, Indian Medical Association, New Delhi (Member).
5. Dr. Agam Vora, Org. Secretary, Indian Medical Association, Mumbai (Member).
6. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
7. Dr. Sandeep B. Bavdekar, Former Prof. Head Pediatrics T. N. Medical College BYL Nair Hospital, Mumbai (Co-opted Member).
8. Shri. Sanjeev Kumar, Deputy Drugs Controller (India), CDSCO (HQ), New Delhi; (Convener).

The Convener welcomed the members of the Committee. He informed the Sub-Committee about the action taken on the minutes of the last meeting. He informed the members that the notices for the petitioners including AIDAN were placed on CDSCO website and were also informed through speed post. He apprised the members about the replies received from petitioners including AIDAN. It was informed that 501 letters were issued to the petitioners/appellants. In response to these letters, about 674 replies have been received so far from different petitioners/appellants. The Committee was also apprised that these 674 replies correspond to about 136 FDCs. It was also informed that about 36 letters couldn't be delivered and received back as addressee is not found.

The Committee then considered various representations received. Representations were received from AIDAN, IDMA, FOPE, M/s Abbott Healthcare and Association of Dermatologists, Venereologists and Leprologists. As regard to representation received from Association of Dermatologists, Venereologists and Leprologists, the Sub-Committee noted the representation. Sub-Committee requested the Member Secretory to place all these representations before DTAB for the needful.

626

Considering the request for additional time and the time limit set by the Hon'ble Supreme Court, the Sub-Committee decided to extend the last date of submission of reply in the format provided Annexure A/D to 2nd May 2018 till 5.00 PM for all. This will be put on the CDSCO website for information to all and specifically for those who have made the representations.

Sub-Committee then finalised the schedule for conducting meeting for obtaining Co-opted Subject Experts opinion on all the 349 FDCs. The schedule is annexed. The Member Secretory will forward the invitation letter for inviting the Subject Experts. Format for Subject Expert opinion was reviewed, modified and is annexed. The next meeting of Sub-Committee will be held on 29th May 2018 (to be confirmed). The Member Secretory was requested to prepare the schedule for hearings of petitioners for the month of June 2018.

The meeting ended with vote of thanks to the Chair.

Annexure A

Format for submission of information by appellant/petitioner on FDC to DTAB Sub-Committee

(Submit information as hard copy as well as soft copy)

S. No.	Item	Response	
1.	(a) Composition of Product: (Details of all strengths/ dosage forms)		
	(b) Brand name/s, if any:		
	(c) Name of the Applicant, specify if i. Manufacturer: ii. Marketer : iii. Petitioner/appellant		
	(d) Approving authority with year of approval	Name of the Authority	Year of Approval

Signature of the Authorized representative: _____

Name: _____

Designation: _____

Date: _____

Place: _____

Communication (Address, Telephone, Email) Details:

Company Seal:

For Office Use:	
Identification No. Company	

621-A

Identification No. (Office Use)	

S. No.	Item	Response
2.	Particulars of the drug: Dosage form, composition of the formulation (including all active ingredients, pharmacological classification)	
3.	Indication(s)	
4.	Provide a copy of Package insert as per Schedule Y of Drugs & Cosmetics Rules.	
5.	State the category (as per Appendix VI) under which FDC approval is claimed	
6.	a) Therapeutic justification / rationale for each ingredient and quantity in the FDC	
	b) Therapeutic value claimed or purported to be claimed of the FDC (Postulated advantage/ value of FDC) (Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five relevant full text articles in peer-reviewed journals/ relevant pages from textbooks) [Tick (√) appropriate option(s)]	
	i. Increased efficacy	
	ii. Reduced incidence and/or severity of adverse effects	
	iii. Dose reduction	
	iv. Reduced cost	
	v. Booster for another drug	
	vi. Improved patient adherence/ Convenience	
	vii. Minimization of abuse of other actives	
	viii. Simpler logistics of procurement and/ or distribution	
	ix. Reduced development of microbial resistance	
	x. Any other (please specify)	

621- B

(Office Use)	

S. No.	Item	Response
7.	Pharmacokinetic/ pharmacodynamics rationality with half-life details of individual ingredients, dosage schedule of individual drugs (Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/ rationale. The evidence should be enclosed in the form of maximum of five relevant full text articles in peer-reviewed journals/ relevant pages from textbooks)	
8.	Published data regarding safety and efficacy of FDC (Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five relevant full text articles in peer-reviewed journals/ relevant pages from textbooks)	
9.	Original Safety & Efficacy data if any, regarding the FDC, generated by the applicant (Submit a one-page summary. Also submit the article based on these data, if published or one-page abstract of each study if unpublished with CTRI number, if available)	
10.	Regulatory status of the FDC in other countries	
10.1	Countries where the drug is:	
	(a) Marketed	
	(b) Approved	
	(c) Approved as IND	
	(d) withdrawn, if any, with reasons	
10.2	Restrictions on use, if any, in countries where marketed/ approved	
11	Specimen of labels and cartons	
12	Any other relevant information	
13	Submit PPT of presentation in hard copy (Maximum 7 slides) which the company will present to the committee	

(Note: Individual Form shall be submitted for each FDC and all above information shall be provided for each strength/ dosage form for an FDC in the same form or separate form if required)

621-C

Annexure D

Format for submission of information on FDC to DTAB Sub-Committee by All India Drug Action Network (AIDAN)

(Submit information as hard copy as well as soft copy)

For Office Use:	
Identification No.	

1. Composition / product details

Dosage form:

Sr. No.	Ingredient	Quantity

2. Is there therapeutic justification for each ingredients and the quantity of each ingredient in FDC ?(Please provide one page summary of justification/ rationale/ basis for your opinion with supporting scientific evidence as maximum five relevant published articles)

3. Does the FDC have therapeutic value claimed/ purported to be claimed?
(Please provide one page summary of justification/ rationale/ basis for your opinion with supporting scientific evidence as maximum five relevant published articles)

4. Is the FDC likely to involve any risk to human beings or animals?
(Please provide one page summary of justification/ rationale/ basis for your opinion with supporting scientific evidence as maximum five relevant published articles)

5. In AIDAN opinion, in public interest is restriction or regulation sufficient instead of prohibition to control the manufacturer and use of FDC.

(Note: Individual Form shall be submitted for each FDC and all above information shall be provided for each strength/ dosage form for an FDC in the same form or in separate form if required)

Name of the AIDAN representative filing the information: _____

Designation: _____

Signature and Date: _____

Seal

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 07.05.2018 to 08.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai.
3. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai.
4. Dr. Subhash Giri, Director & Prof., of Medicine, University College of Medical Sciences (UCMS), New Delhi.
5. Dr. Renuka Munshi, Associate Prof. & In-Charge of Department of Clinical Pharmacology, B. Y. L. Nair Charitable Hospital, Dr. A. L. Nair Road, Mumbai.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Pulmonary category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 37 FDCs of Pulmonary category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 09.05.2018 to 10.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai.
3. Dr. Subhash Giri, Director & Prof., of Medicine, University College of Medical Sciences (UCMS), New Delhi.
4. Dr. Mira Desai, Prof. & Head Dept. of Pharmacology, BJ Medical College, New Civil Hospital, Asarwa, Ahmedabad, Gujarat.
5. Dr. Subodh Kumar, Asst. Prof., Dept. of Pulmonary Medicine, All India Institute of Medical Sciences, Rishikesh, Virbhadra Road, Near Barrage, Rishikesh, Uttarakhand.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Pulmonary category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 56 FDCs of Pulmonary category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 11.05.2018 to 12.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai.
3. Dr. B. Gupta, Prof. in General Medicine, North Delhi Medical College & Hindu Rao Hospital, New Delhi.
4. Dr. Sujith Chandy, Prof. & Dept. of Pharmacology, CMC, Christian Medical College & Hospital, Vellore.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Medicine category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 22 FDCs of Medicine category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 14.05.2018 to 15.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai.
3. Dr. Sushant H. Meshram, Professor, Government Medical College & Hospital Nagpur.
4. Dr. Deepak Aggarwal, Associate Professor, Pulmonary Medicine, Govt. Medical College, Chandigarh.
5. Dr. B. Gupta, Prof & Head, Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi.
6. Dr. Bikash Medhi, Professor, Dept. of Pharmacology, PGIMER, Chandigarh.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Pulmonary category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 39 FDCs of Pulmonary category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 16.05.2018 to 17.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai.
3. Dr. Deepak Aggarwal, Associate Professor, Pulmonary Medicine, Govt. Medical College, Chandigarh.
4. Dr. B. Gupta, Prof. in General Medicine, North Delhi Medical College & Hindu Rao Hospital, New Delhi.
5. Dr. Anant Mohan, Additional Professor, Pulmonary Medicine, AIIMS, New Delhi.
6. Dr. Abhishek Agrawal, Professor, Dept. Of Medicine, SMS Medical College, Jaipur.
7. Dr. Dinesh Badyal, Prof & Head, Department of Pharmacology, Christian Medical College & Hospital, Ludhiana.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Pulmonary category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 31 FDCs of Pulmonary category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 18.05.2018 to 19.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai.
3. Dr. R. K. Arya, Consultant & HOD, Dept. Of Orthopaedics, RML Hospital New Delhi.
4. Dr. Abhishek Agrawal, Professor, Dept. Of Medicine, SMS Medical College, Jaipur.
5. Dr. B. Gupta, Prof & Head, Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi.
6. Dr. Avijit Hazra, Professor, Department of Pharmacology, IPGME&R, Kolkata.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Analgesic category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 37 FDCs of Analgesic category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

627

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 21.05.2018 to 22.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai.
3. Dr. V. K. Sharma, Prof. and Head, Dept. of Dermatology, AIIMS, New Delhi.
4. Dr. K. M. K. Reddy, Prof. & Head, Dept. of Cardiology, Osmania Medical College, Hyderabad.
5. Dr. Sanjeev Handa, Professor and Head, Dept. of Dermatology, Venereology & Leprology, PGIMER, Chandigarh.
6. Dr. B. Gupta, Prof & Head, Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi.
7. Dr. Suparna Chatterjee, Professor, Dept. of Pharmacology, Institute of Post Graduate Medical Education and Research, Kolkata.
8. Dr. Rohit Saxena, Professor of Ophthalmology, Dr. R. P. Centre for Ophthalmic sciences, AIIMS, Delhi.
9. Dr. Arvind Kairo, Asst. Professor, Dept. Of Otolaryngology, Head and Neck Surgery, AIIMS, New Delhi.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Dermatology, Cardiology, ENT and Ophthalmology category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 39 FDCs of Dermatology, Cardiology, ENT and Ophthalmology category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 23.05.2018 to 24.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Vyankatesh Shivane, Consultant Diabetologist, Mumbai.
3. Dr. B. Gupta, Prof & Head, Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi.
4. Dr. Chetna Desai, Prof. Dept. of Pharmacology, BJ Medical College, Ahmedabad.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Endocrinology category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 29 FDCs of Endocrinology category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 23.05.2018 to 24.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1 Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2 Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai.
3 Dr. Harshad Devarbhavi, Professor of Gastroenterology at St. John's Medical College and Hospital, Bangalore.
4 Dr Santanu Tripathi, Professor of Clinical Pharmacology, Calcutta School of Tropical Medicine, Kolkata.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Gastroenterology category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 42 FDCs of Gastroenterology category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 25.05.2018 for examination of cases of banning of 344 FDCs + 05 FDCs.

Members present:

1. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai.
2. Dr. Anup Kumar Kundu, Prof. & Head, Dept. of Urology, IPGMER & SSKM, Kolkata.
3. Dr. Chetna Desai, Prof. Dept. of Pharmacology, BJ Medical College, Ahmedabad.
4. Dr. B. Gupta, Prof & Head, Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi.
5. Dr. Pikee Saxena, Professor, Dept. Of Obstetrics & Gynaecology, Lady Harding Collage, New Delhi.
6. Dr. Debashish Choudhary, Director-Professor & HOD OF Neurology, GB Pant, New Delhi.
7. Dr. Kameshwar Prasad, Prof. & Head, Dept. of Neurology, AIIMS, New Delhi.

The chairperson welcomed all the members as well as co-opted experts and briefed that we will be discussing FDCs pertaining to Urology, Gynecology and Neurology category in accordance with the directions of Hon'ble Supreme Court. The chairperson also briefed that these meetings will be followed by hearing from the petitioners/appellants including AIDAN.

Accordingly, the committee discussed 17 FDCs corresponding to approx. 34 receipts received of Urology, Gynecology and Neurology category. During discussion, the committee also noted the replies submitted by various companies including AIDAN and concluded that final recommendation will be made after giving hearing to appellants/petitioners including AIDAN.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 05.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. R. N. Tandon, Honorary Secretary General, Indian Medical Association, New Delhi (Member).
4. Dr. Agam Vora, Org. Secretary, Indian Medical Association, Mumbai (Member).
5. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
6. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
7. Dr. Abhishek Agarwal (Asso Prof), Deptt. Of Medicine, Sawai Man Singh Medical College, J.L.N. Marg, Near Albert Hall Museum, Ram Niwas Garden, Jaipur, Rajasthan.
8. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies from today onwards on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	777	DWD Pharma & Coral Pharma (made common presentation)
2	968	Anglo French
3	977	Laborate Pharmaceuticals
4	977	Akums and Cipla (made common presentation)
5	977	Horizon Bioceuticals
6	979	Horizon Bioceuticals
7	985	Akums
8	985	IND Swift
9	985	Horizon Bioceuticals

Committee noted that for S.O.s: 723, 726, 749, 869, 872, 877, 880, 967 and 986, no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 06.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
4. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
5. Dr. Abhishek Agarwal (Asso Prof), Deptt. Of Medicine, Sawai Man Singh Medical College, J.L.N. Marg, Near Albert Hall Museum, Ram Niwas Garden, Jaipur, Rajasthan.
6. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	707	Horizon Bioceuticals
2	707	Akums
3	709	Akums
4	713	Remidex Pharma-GSK (made common presentation)
5	713	Reckitt Benckiser
6	713	Akums
7	713	Proctor & Gamble hygiene
8	740	Varav Biogenesis
9	740	Nulife Pharmaceuticals
10	781	FDC Ltd.+ Accent Pharma+ Akums (made common presentation)
11	789	Abbott Healthcare + Varav biogenesis+ Mankind Pharma+ Acron Pharmaceuticals (made common presentation)
12	859	Akums
13	860	Akums
14	861	Merck Limited + Tidal Laboratories + Akums (made common presentation)
15	862	Alkem+ Akums+ Elnova Pharma (made common presentation)
16	863	Akums
17	864	Akums
18	887	Varav Biogenesis

19	889	Varav Biogenesis
20	988	Indoco Remedies
21	988	Centaur Pharma
22	988	Akums
23	988	IPCA
24	988	Wings Pharmaceuticals
25	997	Retort Laboratories
26	998	Retort Laboratories
27	1005	Cipla + Akums+ Alkem+ FDC (made common presentation)
28	1005	Varav Biogenesis (Horizon)
29	1030	IPCA
30	1030	Indico Remedis
31	1033	Systopic
32	1034	Centaur Pharma
33	1035	Centaur Pharma
34	1039	Nulife Pharma
35	1047	Nulife Pharma

Committee noted that for S.O.s: 881, 882, 884, 886, 902, 914, 991, 992, 993, 994, 995, 996, 999, 1000, 1024 and 1037, no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 07.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. R. N. Tandon, Honorary Secretary General, Indian Medical Association, New Delhi (Member).
4. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
5. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
6. Dr. B. Gupta, Prof. in General Medicine, North Delhi Medical Collage & Hindu Rao Hospital, DR. J.S. Kkaranwal Memorial Road, Near Malka Ganj, Sabji Mandi, Malka Ganj, New Delhi.
7. Dr. Bikash Medhi, Deptt. Of Pharmacology, Post Graduate Medical Education and Research (PGIMER), Sector-12, Chandigarh.
8. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	S.O. 865 (E)	Akums
2	S.O. 867 (E)	Akums
3	S.O. 868 (E)	SKN Organics
4	S.O. 870 (E)	GSK + alkem + Cipla + juggat + Ind swift (made common presentation)
5	S.O. 871 (E)	Akums
6	S.O. 871 (E)	Bluecross + Hema + Mepromax (made common presentation)
7	S.O. 873 (E)	Mascot Health
8	S.O. 873 (E)	Akums
9	S.O. 874 (E)	Akums
10	S.O. 875 (E)	Mankind Pharma
11	S.O. 875 (E)	Zuventus Healthcare
12	S.O. 875 (E)	Varav Biogenesis
13	S.O. 876 (E)	Varav Biogenesis
14	S.O. 878 (E)	Glenmark
15	S.O. 883 (E)	Lark Laboratories (India) Ltd
16	S.O. 888 (E)	Skan Research
17	S.O. 890 (E)	Akums
18	S.O. 890 (E)	Varav Biogenesis

19	S.O. 893 (E)	Skan Research
20	S.O. 894 (E)	Indswift + cipla + skan (made Common Presentation)

Committee noted that for S.O.s: S.O. 866 (E), S.O. 879 (E), S.O. 891 (E), S.O. 892 (E), S.O. 895 (E), S.O. 897 (E), S.O. 898 (E), S.O. 899 (E), S.O. 923 (E), S.O. 937 (E), S.O. 1001 (E), S.O. 1023 (E), S.O. 1026 (E) and S.O. 1032 (E), no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 08.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. R. N. Tandon, Honorary Secretary General, Indian Medical Association, New Delhi (Member).
4. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
5. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
6. Dr. B. Gupta, Prof . in General Medicine, North Delhi Medical Collage & Hindu Rao Hospital, DR. J.S. Kkaranwal Memorial Road, Near Malka Ganj, Sabji Mandi, Malka Ganj, New Delhi.
7. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	900	Acron
2	901	Windlas , Lincolin (made common presentation)
3	903	Tablets India
4	905	Cipla , Shreya (made common presentation)
5	906	Windlas , Lincolin (made common presentation)
6	908	Alembic , Akums , Laborate (made common presentation)
7	909	Abbott , Mankind , Dr Reddys , Khandelwal , Laborate, Anglo french , Laboratories Griffon , Acron , Ozone , Somatico, Varav , Merck , Glenmark , Lincolin , Windlas , Wings , Shreya (made common presentation)
8	910	Apex , Laborate, Varav (made common presentation)
9	911	Varav
10	912	Koye , Macleods , Akums , Mascot , Macsur (made common presentation)
11	913	Jenburkt
12	920	Abbott
13	922	Akums
14	926	Alkem , Akums , Laborate , Ind swift (made common presentation)
15	929	Varav, Synchem (made common presentation)
16	930	Alkem , Magnet , Cadila , Mascot, Laboraties Griffon

		(made common presentation)
17	932	Alembic , Akums (made common presentation)
18	935	Indico remedies , Laborate (made common presentation)

Committee noted that for S.O.s: 896, 907, 915, 917, 918, 919, 921, 924, 925, 927, 928, 931, 933, 934, 939, 942, 943, 945, 947, 948, 951, and 955 no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 09.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
4. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
5. Dr. B. Gupta, Prof . in General Medicine, North Delhi Medical Collage & Hindu Rao Hospital, DR. J.S. Kkaranwal Memorial Road, Near Malka Ganj, Sabji Mandi, Malka Ganj, New Delhi.
6. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	936	Biological E Limited
2	938	Uni-san
3	941	Lark
4	946	Varav
5	949	Unison
6	949	Centaur , Mascot (made common presentation)
7	950	Centaur
8	950	Alembic , Alkem , Cipla , Unison , Akums , Horizon , Juggat , Lark , Lifestar , Microlabs , Wings , Mascot , Ind swift (made common presentation)
9	990	Wings

Committee noted that for S.O.s: 940, 944, 952, 958, 960, 966, 969, 970, 971, 972, 973, 974, 975, 978, 980, 981, 982, 983, 984, 987, 989, 1851 and 1853 no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 11.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
4. Dr. Renuka Munshi, Associate Prof. & In-Charge of Department of Clinical Pharmacology, B. Y. L. Nair Charitable Hospital, Dr. A. L. Nair Road, Mumbai.
5. Dr. Anant Mohan, Professor, Pulmonary Medicine, AIIMS, New Delhi.
6. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	954	Akums + Wings + Mascot (made common presentation)
2	954	JB chemicals
3	954	Synchem
4	961	Spectrum
5	962	Firm submitted copy of presentation, but did not make a presentation to sub-committee.
6	963	Wings
7	964	Wings
8	965	Alkem

Committee noted that for S.O.s: S.O. 953, 956, 957 and 959 no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 12.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
4. Dr. Chetna Desai, Prof. Dept. of Pharmacology, BJ Medical College, Ahmedabad
5. Dr. Vyankatesh Shivane, Consultant Diabetologist, King Edward Memorial Hospital, Acharya Donde Marg, Parel, Mumbai.
6. Dr. Rajesh Khadgawat, Professor, Dept. of Endocrinology, All India Institute of Medical Sciences, (AIIMS), Ansari Nagar, New Delhi.
7. Sh. Sanjeev Kumar, Convener, DDC (I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	773	Centaur , Glenmark , Akums , Coral , DWD Pharma , Jenbutkt , Pharmasynth , Mankind (made common presentation)
2	785	Akums , GKM New Pharma (made common presentation)
3	802	Microlabs , Unison , Franco-Indian , Inventia , Emcure , Aristo , Lupin , Eris , Cipla, ACME generics , Akumenties , Akums ,Systopic , Madras , Accent , Hetero , Anfar , Trister (made common presentation)
4	802	SUN
5	805	USV , Franco Indian , Lupin , Madras , Maral (made common presentation)
6	806	Microlabs , Cipla , Lupin , Sun (made common presentation)
7	806	USV
8	807	ERIS
9	808	Mankind
10	809	Mankind
11	810	Inventia
12	813	Aeon
13	814	Lupin , Mankind , Inventia , USV (made common presentation)
14	814	SUN
15	818	Panacea Biotec , Alembic (made common presentation)
16	822	Microlabs , USV , Mankind , GKM New Pharma , Lupin (made common presentation)
17	822	SUN

18	825	Glenmark , Akums , FDC , Mankind , Pharmasynth , Elan (made common presentation)
19	1048	NuLife

Committee noted that for S.O.s: 803, 804, 811, 812, 828, 829, 830 and 831 no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 13.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. R. N. Tandon, Honorary Secretary General, Indian Medical Association, New Delhi (Member).
3. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
4. Dr. Chetna Desai, Prof. Dept. of Pharmacology, BJ Medical College, Ahmedabad.
5. Dr. Vyankatesh Shivane, Consultant Diabetologist, King Edward Memorial Hospital, Acharya Donde Marg, Parel, Mumbai.
6. Dr. Rajesh Rajput, Senior Prof. & Head, Dept. of Endocrinology, Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences (PGIMS), Medical Rd, Rohtak, Haryana.
7. Dr. Arvind Kairo, Asst. Professor, Dept. of Otolaryngology, Head and Neck Surgery, AIIMS, Main Hospital, Ansari Nagar, in front of Safdarjung Hospital, New Delhi.
8. Sh. Sanjeev Kumar, Convener, DDC (I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	815	Lupin, Abbott, Systopic, Unison, Sanofi, ACME, FDC, Alkem, Intas, Cipla, Akums, Dr Reddys, Mankind, Ozone, Franco Indian, Hetero, Microlabs, GKM new Pharma, Torrent, Alembic, Wings, Emcure, Aristo, Indico remidies, Zuventus, Inventia, Accent, USV, Macleods, Tristar and Madras (made common presentation)
2	815	Sun Pharma
3	823	Cipla and Mankind (made common presentation)

Committee noted that for S.O.s: 816, 817, 819, 820, 821, 824, 857, 1029, 1043, 1044 and 1045 no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 14.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
3. Dr. B. Gupta, Prof . in General Medicine, North Delhi Medical Collage & Hindu Rao Hospital, DR. J.S. Kkaranwal Memorial Road, Near Malka Ganj, Sabji Mandi, Malka Ganj, New Delhi, Delhi.
4. Dr. Sujith Chandy, Prof. & Dept. of Pharmacology, CMC, Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu.
5. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	752	Zuventus, Khandelwal, Aristo, Mascot, Magnet, Hetero, Horizon, Akums, Macleods, FDC Ltd, Ozone Pharma, Alkem, Aeon, Emcure, MicroLab, Ind Swift, Wings (made common presentation)
2	753	Alkem, Cipla, Ind Swift, Lupin, Unimedical, Micro Labs, Laborate Pharma, Wings Pharma, Akums (made common presentation)
3	755	Hetero, Akums, Macleods Akums (made common presentation)
4	756	Alkem, Aristo, FDC, Hetero, Macleods, MicroLabs, Akums Akums (made common presentation)
5	759	Lupin, Macleods, Mankind, Mascot, Akums Akums (made common presentation)
6	792	Unisan

Committee noted that for S.O.s: 754, 757, 761, 765, 771, 779, 780, 835, 904, 1008, 1042 and 1046 no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 15.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
3. Dr. B. Gupta, Prof . in General Medicine, North Delhi Medical Collage & Hindu Rao Hospital, DR. J.S. Kkaranwal Memorial Road, Near Malka Ganj, Sabji Mandi, Malka Ganj, New Delhi, Delhi.
4. Dr. Sujith Chandy, Prof. & Dept. of Pharmacology, CMC, Christian Medical College & Hospital, Ida Scudder Road, Vellore, Tamil Nadu.
5. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	S.O. 760 (E)	FDC, DWD/Coral, Hetero Healthcare, Akums, Acme (made common presentation)
2	S.O. 763 (E)	Alkem, Aeon Formulations (made common presentation)
3	S.O. 766 (E)	Akums
4	S.O. 769 (E)	Systopic
5	S.O. 770 (E)	Tidal Lab, Aeon Formulations (made common presentation)
6	S.O. 772 (E)	Aeon Formulations, Macleods, Hetro Healthcare, Akums, Hetro, wings, Obsurge, Akums, Lifestar, Mascot (made common presentation),
7	S.O. 772 (E)	Sun Pharma
8	S.O. 774 (E)	Macleods, Micro Lab, Mascot, Akums (made common presentation)
9	S.O. 774 (E)	Koye

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 18.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
4. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
5. Dr. B. Gupta, Prof . in General Medicine, North Delhi Medical Collage & Hindu Rao Hospital, DR. J.S. Kkaranwal Memorial Road, Near Malka Ganj, Sabji Mandi, Malka Ganj, New Delhi, Delhi.
6. Dr. Avijit Hazra, Professor, Dept. of Pharmacology, Institute of Post Graduate Medical Education and Research, (IPGMER) & SSKM, Kolkatta.
7. Dr. R. K. Arya, Consultant & HOD, Dept. of Orthopaedics, Ram Manohar Lohia Hospital (RML), Baba Kharak Singh Marg, New Delhi.
8. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	S.O. 705 (E)	Akums, Mascot, Wockhardt (made common presentation)
2	S.O. 706 (E)	Emcure, Akums, Alkem Labs, Emcure, Horizon (made common presentation)
3	S.O. 708 (E)	Dr. Reddy's, Akums, Unisan Pharma, Wings Pharma (made common presentation)
4	S.O. 710 (E)	Mascot
5	S.O. 712 (E)	Akums
6	S.O. 717 (E)	TTK Healthcare, Ruby Organics, Horizon, Akums, Mascot (made common presentation)
7	S.O. 720 (E)	Akums
8	S.O. 724 (E)	Akums
9	S.O. 725 (E)	Laborate, Horizon (made common presentation)
10	S.O. 731 (E)	Aeon Formulations
11	S.O. 735 (E)	Ajanta Pharma
12	S.O. 736 (E)	Sundyota

13	S.O. 737 (E)	Sundyota
14	S.O. 738 (E)	Horizon
15	S.O. 751 (E)	Akums

Committee noted that for S.O.s: 714, 716, 719, 721, 727, 728, 732, 733, 743, 746, 748 and 1025 no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 19.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
4. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
5. Dr. B. Gupta, Prof . in General Medicine, North Delhi Medical Collage & Hindu Rao Hospital, DR. J.S. Kkaranwal Memorial Road, Near Malka Ganj, Sabji Mandi, Malka Ganj, New Delhi, Delhi.
6. Dr. Avijit Hazra, Professor, Dept. of Pharmacology, Institute of Post Graduate Medical Education and Research, (IPGMER) & SSKM, Kolkatta.
7. Dr Santanu Tripathi, Professor of Clinical Pharmacology, Calcutta School of Tropical Medicine, Kolkata
8. Dr. B. C. Sharma, Professor, Dept. of Gastroenterology, G.B Pant Hospital, New Delhi
9. Dr. Vijay kumar Jain, Associate Prof. Orthopedics, RML hospital, New Delhi.
10. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	S.O. 715 (E)	Horizon Bioceuticals
2	S.O. 718 (E)	Horizon Bioceuticals
3	S.O. 730 (E)	Horizon Bioceuticals
4	S.O. 739 (E)	Akums
5	S.O. 742 (E)	Horizon Bioceuticals, Mascot Health Sciences (Made Common Presentation)
6	S.O. 747 (E)	Strassenburg
7	S.O. 750 (E)	FDC Limited
8	S.O. 758 (E)	Ind-Swift Ltd., Mankind, Horizon Bioceuticals, Lupin Limited, Akums (Made common representation)
9	S.O. 832 (E)	Tidal Labs, Horizon Bioceuticals, Akums, Mankind (Made common representation)
10	S.O. 1027 (E)	Inga laboratories

11	S.O. 1036 (E)	Piramal Enterprises, Ajanta, Juggat Pharma (Made common representation)
12	S.O.1855 (E)	IPCA, Mankind, Lupin Limited, Wanbury Ltd. (Made common representation)
13	S.O.1855 (E)	Zuventus, Emcure (Made Common Presentation)

Committee noted that for S.O.s: 711 (E), 729 (E), 744 (E), 745 (E), 767 (E), 768 (E), 775 (E), 846 (E), 847 (E), 848 (E), 849 (E), 851 (E), 852 (E), 885 (E), 1854 (E) no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 20.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
4. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
5. Dr. B. Gupta, Prof . in General Medicine, North Delhi Medical Collage & Hindu Rao Hospital, DR. J.S. Kkaranwal Memorial Road, Near Malka Ganj, Sabji Mandi, Malka Ganj, New Delhi, Delhi.
6. Dr Santanu Tripathi, Professor of Clinical Pharmacology, Calcutta School of Tropical Medicine, Kolkata
7. Dr. B. C. Sharma, Professor, Dept. of Gastroenterology, G.B Pant Hospital, New Delhi
8. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The committee also heard AIDAN with respect to all the 344 FDCs + 5 FDCS. The details which were presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	S.O. 762 (E)	Lupin Limited for Safetab
2	S.O. 764 (E)	Dr. Reddys Limited
3	S.O. 776 (E)	JB Chemicals & Pharmaceuticals ltd., Lark Laboratories (Made common presentation)
4	S.O. 776 (E)	Sun Pharma
5	S.O. 794 (E)	Aeon Formulations
6	S.O. 801 (E)	Micro Labs, GKM, Aeon, Pharmed Limited, Macleods Pharma, Akums, Lupin Limited, Saichem Pharma (Made common presentation)
7	S.O. 843 (E)	Horizon Bioceuticals, Lark Laboratories (Made common presentation)
8	S.O. 1031 (E)	Ozone Pharmaceuticals, Akums, Mascot Health Series, Mankind Pharma, Ind Swift Ltd., Chemonix India, Zuventus, Alkem, Macleods Pharma, Micro lab Ltd.
9	S.O. 1031 (E)	Mendine Pharmaceuticals Pvt. Ltd.
10	S.O.1852 (E)	Mankind, Ak ums, Zuvenus, Cipla, JB Chemicals and Pharmaceuticals Ltd.
11	NA	AIDAN Representation

Committee noted that for S.O.s: 793 (E), 833 (E), 834 (E), 836 (E), 837 (E), 838 (E), 839 (E), 840 (E), 841 (E), 842 (E), S.O. 844 (E), 845 (E), 850 (E), 853 (E) and 1038 (E) no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 21.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. R. N. Tandon, Honorary Secretary General, Indian Medical Association, New Delhi (Member).
4. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
5. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
6. Dr. Suparna Chatterjee, Professor, Dept. of Pharmacology, Dept. of Pharmacology, Institute of Post Graduate Medical Education and Research, (IPGMER) & SSKM, Kolkata.
7. Dr. V. K. Sharma, Prof. and Head, Dept. of Dermatology, (AIIMS), Main Hospital, Ansari Nagar, In Front Of Safdarjung Hospital, New Delhi.
8. Dr. B. Gupta, Prof . in General Medicine, North Delhi Medical Collage & Hindu Rao Hospital, DR. J.S. Kkaranwal Memorial Road, Near Malka Ganj, Sabji Mandi, Malka Ganj, New Delhi, Delhi.
9. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	S.O. 916 (E)	Centaur Pharma, Akums (Made common presentation)
2	S.O. 976 (E)	Nuflife Pharma
3	S.O. 1006 (E)	Lifestar, Mankind Pharma ltd. (Made common presentation)
4	S.O. 1011 (E)	Universal Twin Labs
5	S.O. 1012 (E)	Universal Twin Labs, Varav Biogenesis, Unimarck
6	S.O. 1013 (E)	Fourrts India
7	S.O. 1018 (E)	Macleods Pharma, Glenmark, Varav biogenesis, Akums, Indswift, Mankind Pharma, Micro labs, Alkem (Made common presentation)
8	S.O. 1019 (E)	Varav biogenesis, Ind swift ltd (Made common presentation)
9	S.O. 1020 (E)	Varav Biogenesis

Committee noted that for S.O.s: 778 (E), 782 (E), 784 (E), 786 (E), 787 (E), 826 (E), 827 (E), 858 (E), 1002 (E), 1003 (E), 1004 (E), 1007 (E), 1009 (E), 1010 (E), 1014 (E), 1015 (E), 1016 (E), 1017

(E), 1021 (E), 1022 (E), 1040 (E) and 1041 (E), no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 22.06.2018 for Hearing Company's representation and examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Joint Commissioner, FDA, Maharashtra (Member).
3. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
4. Dr. Chetna Desai, Prof. Dept. of Pharmacology, BJ Medical College, Ahmedabad.
5. Dr. Pikee Saxena, Professor, Dept. Of Obstetrics & Gynaecology, Lady Harding Collage, C-604, Shaheed Bhagat Singh Road, Diz Area, Connaught Place, New Delhi.
6. Dr. Debashish Choudhary, Director-Professor & HOD OF Neurology, Govind Ballabh Pant Hospital, 1, Jawaharlal Nehru Marg, New Delhi.
7. Dr. Smita N. Deshpande, Prof & Head, Dept. of Psychiatry, Dr. Ram Manohar Lohia Hospital & PGIMER, New Delhi.
8. Dr. Shubhra Gill, Associate Professor, Dept. of Prosthodontics, MAMC, New Delhi.
9. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

The chairperson welcomed all the members and co-opted experts of the sub-committee apprised them about the work done till date. She informed them that as per the public notice published in CDSCO website dated 28th may 2018 the committee will be hearing companies on FDCs in accordance to the schedule provided with the public notice and as per the directions of Hon'ble Supreme Court. The public notice states that in the event that the petitioner does not attend the hearing, the subcommittee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme court. The list of FDCs for which hearing is to be provided today is mentioned under annexure 'X'.

Accordingly, the committee heard the presentations by the companies, replies given by the companies to any queries by the members and also any additional information that they wished to provide. The details of the companies which presented in front of the committee are as follows:

S.No.	S.O. No.	Name of the Firm
1	S.O. 734 (E)	La Pristine Bioceuticals Pvt Ltd.
2	S.O. 741 (E)	Horizon Bioceuticals, Macmillon Pharmaceuticals Ltd. (Made common presentation)
3	S.O. 790 (E)	Varav Biogenesis, ind Swift ltd. (Made common presentation)
4	S.O. 795 (E)	Torrent Pharma, micro labs, intas Pharma (Made common presentation)
5	S.O. 796 (E)	Magnet labs, Akums, Obsurge, Microlabs, Windlas Biotech
6	S.O. 854 (E)	Akums
7	S.O. 855 (E)	Akums, TTK (Made common presentation)
8	S.O. 856 (E)	Wanbury Ltd.
9	S.O. 1028 (E)	Abbott, Anglofrench

Committee noted that for S.O.s: 722(E, 783 (E), 788 (E), 791(E), 797 (E), 798(E), 799 (E) and 800 (E) no firm turned up for presentation/hearing. These S.O.'s were also reviewed by the committee.

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 28.06.2018 to 29.06.2018, 04.07.2018 to 06.07.2018 and 12.07.2018 for examination of cases on banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Dr. Nirmala Rege, Prof. & Head, Dept. of Pharmacology & Therapeutics, Seth GS Medical College, Mumbai (Member).
3. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics T. N. Medical College by Nair Hospital, Mumbai (Co-opted Member).
4. Sh. Sanjeev Kumar, Convener, DDC(I), CDSCO, HQ, New Delhi.

Dr. Nilima Kshirsagar, could not attend the meeting on 12.07.2018

The Subcommittee members examined the analysis w.r.t. hearings provided to the petitioners/appellants including AIDAN. The Subcommittee also prepared a draft report and compiled all the information available before the Subcommittee

The meeting ended with the vote of thanks.

Minutes of the Meeting of Sub-Committee of Drug Technical Advisory Board held on 13th July 2018 for examination of cases of banning of 344 FDCs + 05 FDCs

Members present:

1. Dr. Nilima Kshirsagar, the Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).
2. Sh. O. S. Sadhwani, Former, Joint Commissioner& Drugs Controller, FDA, Maharashtra (Member).
3. Dr. R. N. Tandon, Honorary Secretary General, Indian Medical Association, New Delhi (Member).
4. Dr. Agam Vora, Org. Secretary, Indian Medical Association, Mumbai (Member).
5. Dr. T.V. Narayana, President IPA, 156, 4th Cross, 1st Main Ramanjaneya Nagar, HBSC Lay out, Chikkalasandra, Banglore. (Member)
6. Dr. Sandeep B. Bavdekar, Former Prof. Head Pediatrics T. N. Medical College BYLNair Hospital, Mumbai (Co-opted Member).
7. Shri. Sanjeev Kumar, Deputy Drugs Controller (India), CDSCO (HQ), New Delhi; (Convener).

Dr. Nirmala Rege could not attend the meeting due to prior commitment.

The Convener welcomed the members of DTAB Sub-Committee. The Chairperson thanked all the expert members for attending the meeting and apprised the Committee members about the background with respect to 344+ 5 FDCs.

The Committee was also apprised about the terms of references based on Hon'ble Supreme Court Judgement dated 15.12.2017.

The chairperson also apprised the member that this committee has heard petitioner/appellate including AIDAN and based on the information available, a draft report has been prepared.

The draft report was presented before the DTAB sub-committee which was finalized by all the members of the committee for further placing before DTAB.

Meeting ended with vote of thanks to Chairperson.

File No. 4-01/2013-DC (Misc. 13-PSC-Part-I)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 05 JUN 2018

PUBLIC NOTICE

Subject: **Meeting of DTAB sub Committee w.e.f. 05.06.2018 to 22.06.2018 in the in the office of DCG (I), 1st floor, FDA Bhawan, Kotla Road, Near National Bal Bhawan, New Delhi-110002 to examine the 344 FDCs + 05 FDCs and to provide hearing to the petitioners/appellants -regarding.**

This is in continuation to this office Public Notice dated 28.05.2018 on the subject cited above where in Date and Time of hearing have been mentioned under Annexure 'A' of the notice.

In this regard, it may be informed that all petitioner/appellants are requested to report to this office at 9:30 AM for the purpose of hearing. Further, it may be noted that there is a partial change in time of hearing for 9th and 22nd June 2018. The time of hearing for these dates will be 9:30 AM to 4:30 PM in place of 9:30 AM to 7:00 PM as mentioned earlier under Annexure 'A'.

(Sanjeev Kumar)
DDC(I), CDSCO (HQ) &
Convener, Sub-Committee of DTAB

Copy to:
Indian Drugs Manufacturing Associations IDMA/FOPE/CIPI/IPA-**with the request to communicate it to your members and publicize it widely so that all concerned can avail this opportunity.**

657

File No. 4-01/2013-DC (Misc. 13-PSC-Part-I)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:

PUBLIC NOTICE

28 MAY 2018

Subject: Meeting of DTAB sub Committee w.e.f. 05.06.2018 to 22.06.2018 in the in the office of DCG (I), 1st floor, FDA Bhawan, Kotla Road, Near National Bal Bhawan, New Delhi-110002 to examine the 344 FDCs + 05 FDCs and to provide hearing to the petitioners/appellants -regarding.

As you are aware that the Sub-Committee of DTAB has been constituted under the chair person ship of Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai to examine the banned 344 FDCs + 05 FDCs with S. O. No. 705 (E) to 1048 (E) dated 10.03.2016 and S. O. 1851 (E) to 1855 (E) dated 08.06.2017 respectively.

Accordingly, vide public notice dated 12.03.2018 published on website of CDSCO, it was requested to submit the information in the prescribed format in hard as well as in soft copy.

Now, in compliance to the directions of Hon'ble Supreme Court of India vide dated 15.12.2017, it has been proposed to give hearing to all the petitioners/appellants for deliberation by the Sub-committee.

Accordingly, Sub-Committee invites the concerned applicants for hearing w.e.f. 05.06.2018 to 22.06.2018 w.r.t. FDCs mentioned under annexure A. Date and time of hearing is also mentioned under annexure A.

It is requested that the concerned petitioners/appellants may kindly make it convenient to give a presentation before the DTAB Sub Committee on these FDCs. It would be highly appreciated if the presentations are 'to the point' using the PPT (if) already submitted. In the event that the petitioner does not attend the hearing, the Sub-Committee reserves the right to make its decision on the basis of information before it and according to the direction of Hon'ble Supreme Court.

You are requested to kindly confirm your participation by e-mail at fdcdivision@gmail.com at least 2 days before the scheduled date of meeting.

(Sanjeev Kumar)
DDC(I), CDSCO (HQ) &
Convener, Sub-Committee of DTAB

Encl: Annexure A

Copy to:
Indian Drugs Manufacturing Associations IDMA/FOPE/CIPI/IPA-with the request to communicate it to your members and publicize it widely so that all concerned can avail this opportunity.

658

Annexure A

Sr. No.	Name of FDC	S.O.Number	Date and time of hearing
1.	Terbutaline Sulphate+Etofylline+Ambroxol	S.O. 967 (E)	05th June 2018 01:30 pm to 07:00pm
2.	Paracetamol +Codeine +Chlorpheniramine	S.O. 968 (E)	
3.	Paracetamol+Bromhexine +Phenylephrine +Chlorpheniramine +Guaifenesin	S.O. 977 (E)	
4.	Dextromethorphan +Phenylephrine +Guaifenesin +Cetirizine +Acetaminophen	S.O. 979 (E)	
5.	Cetirizine +Phenylephrine +Paracetamol +Caffeine +Nimesulide	S.O. 985 (E)	
6.	Dextromethorphan +Cetirizine +Guaifenesin +Ammonium Chloride	S.O. 986 (E)	
7.	Paracetamol +Phenylephirine +Chlorpheniramine +Dextromethorphan +Caffeine	S.O. 723 (E)	
8.	Paracetamol + pseudoephdrine + cetrizine	S.O. 726 (E)	
9.	Paracetamol + Caffeine + Codeine Phosphate	S.O. 749 (E)	
10.	Amoxicillin+Bromhexine	S.O. 777 (E)	
11.	chlorpheniramine maleate+ dextromethophan+ dextromethophan + guaiphenesin + ammonium chloride + menthol	S.O. 869 (E)	
12.	Ambroxol +Guaiphenesin +Ammonium Chloride +Phenylephrine +Chlorpheniramine Maleate +Menthol	S.O. 872 (E)	
13.	chlorpheniramine + phenylephrine + caffiene	S.O. 877 (E)	
14.	dextromethorphan + phenylephrine + zinc gluconate+ menthol	S.O. 880 (E)	

Sr.No.	Name of FDC	S.O. Number	Date and time of hearing
1.	Paracetamol +Chlorpheniramine +Ambroxol +Guaifenesin +Phenylephrine	S.O. 988 (E)	06th June 2018 09:30 am to 07:00pm
2.	Chlorpheniramine +Vitamin C	S.O. 997 (E)	
3.	Calcium Gluconate +Chlorpheniramine +Vitamin C	S.O. 998 (E)	
4.	Chlorpheniramine+Paracetamol +Pseudoephedrine +Caffeine	S.O. 999 (E)	
5.	levocetirizine + ambroxol + phenylephrine + paracetamol	S.O. 1005 (E)	
6.	Dextromethophan +Chlopheniramine +Bromhexine	S.O. 1024 (E)	
7.	Paracetamol + Ambroxol + Phenylephrine +Chlorpheniramine	S.O. 1030 (E)	
8.	Albuterol + Bromhexine + Theophylline	S.O. 1033 (E)	
9.	Salbutamol + Hydroxyethyltheophylline (Etofylline)+ Bromhexine	S.O. 1034 (E)	
10.	Paracetamol +Phenylephrine +Levocetirizine +Sodium Citrate	S.O. 1035 (E)	
11.	Guaifenesin +Diphenhydramine +Bromhexine +Phenylephrine	S.O. 1037 (E)	
12.	Bromhexine +Phenylephrine +Chlorpheniramine +Paracetamol	S.O. 1039 (E)	
13.	Phenylephrine +Chlorpheniramine +Paracetamol +Bromhexine +Caffeine	S.O. 1047 (E)	
14.	Nimesulide + Cetirizine +Caffeine	S.O. 707 (E)	
15.	Paracetamol + cetrizine + caffeine	S.O. 709 (E)	
16.	Paracetamol + Phenylephrine + Caffeine	S.O. 713 (E)	
17.	Ammonium Chloride +Sodium Citrate +Chlorpheniramine Maleate +Menthol	S.O. 740 (E)	

18.	Azithromycin + Ambroxol	S.O. 781 (E)	06th June 2018 09:30 am to 07:00pm
19.	pholcodine +Promethazine	S.O. 789 (E)	
20.	Dextromethorphan + Levocetirizine +Phenylephrine +Zinc	S.O. 859 (E)	
21.	Nimesulide +Loratadine +Phenylephrine +Ambroxol	S.O. 860 (E)	
22.	Bromhexine +Phenylephrine +Chlorepheniramine Maleate	S.O. 861 (E)	
23.	Dextromethorphan + bromhexine +Guaiphenesin	S.O. 862 (E)	
24.	Paracetamol + Loratadine + phenylephrine + Dextromethorphan + caffeine	S.O. 863 (E)	
25.	Nimesulide + Phenylephrine + Ceffeine+ levocetirizine	S.O. 864 (E)	
26.	chlorpheniramine + codeine + sodium citarte + menthol syrup	S.O. 881 (E)	
27.	Enrofloxacin + bromhexin	S.O. 882 (E)	
28.	Levofloxacin +Bromhexine	S.O. 884 (E)	
29.	Levocetirizine +Phenylephrine +Ambroxol +Guaiphenesin +Paracetamol	S.O. 886 (E)	
30.	cetirizine + dextromethorphan + phenylephrine + zinc gluconate + paracetamol+ menthol	S.O. 887 (E)	
31.	diphenhydamine + guaiphenesin + ammonium chloride + bromhexine	S.O. 889 (E)	
32.	dextromethorphan + ambroxol + guaifenesin + phenylephrine + chlorpheniramine	S.O. 902 (E)	
33.	Dextromethorphan +bromhexine +Guaiphenesin+menthol	S.O. 914 (E)	
34.	Dextromethorphan +Ambroxol +Ammonium Chloride +Chlorpheniramine +Menthol	S.O. 991 (E)	

35.	Dextromethorphan +Phenylephrine +Cetirizine +Zinc +Menthol	S.O. 992 (E)	06th June 2018 09:30 am to 07:00pm
36.	Terbutaline + N-Acetyl L-Cysteine + Guaifenesin	S.O. 993 (E)	
37.	Calcium Gluconate +Levocetirizine	S.O. 994 (E)	
38.	Paracetamol +Levocetirizine+Pseudoephedrine	S.O. 995 (E)	
39.	Salbutamol +Choline Theophylinate +Carbocisteine	S.O. 996 (E)	
40.	Guaifenesin +Bromhexine +Chlorpheniramine +Phenylephrine +Paracetamol +Serratiopeptidase (as enteric coated granules)10000 SP Units	S.O. 1000 (E)	

Sr. No.	Name of FDC	S.O.Number	Date and time of hearing
1.	Azithromycin + acebrophyline	S.O. 865 (E)	07th June 2018 09:30 am to 07:00pm
2.	Diphenhydramine +Terpine +Ammonium Chloride +Sodium Chloride +Menthol	S.O. 866 (E)	
3.	Nimesulide+Paracetamol+Cetrizine +Phenylephrine	S.O. 867 (E)	
4.	paracetamol+ loratadine + dextromethophan + pseudoepheridine + caffeine	S.O. 868 (E)	
5.	Chlorpheniramine Maleate+Ammonium Chloride+Sodium Citrate	S.O. 870 (E)	
6.	Cetirizine +Phenylephrine +Paracetamol +Zinc Gluconate	S.O. 871 (E)	
7.	dextromethophen + bromhexine + chlorpheniramine maleate + guaiphenesin	S.O. 873 (E)	
8.	levocetirizine + ambroxol + phenylephrine +guaiphenesin	S.O. 874 (E)	
9.	dextromethorphan + chlorpheniramine + chlorpheniramine maleate	S.O. 875 (E)	
10.	cetirizine + ambroxol + Guaiphenesin + ammonium chloride+ phenylephrine+ menthol	S.O. 876 (E)	
11.	dextromethorphan + triprolidine + phenylephrine	S.O. 878 (E)	
12.	Terpinhydrate+ dextromethorphan + menthol	S.O. 879 (E)	
13.	Bromhexine +Dextromethorphan +Phenylephrine +Menthol	S.O. 883 (E)	
14.	paracetamol+ pseudoephedrine + dextromethorphan + cetirizine	S.O. 888 (E)	
15.	Chlorpheniramine +Dextromethorphan +Phenylephrine +Paracetamol	S.O. 890 (E)	
16.	Dextromethorphen +Promethazine	S.O. 891 (E)	
17.	Diethylcabamazine +Cetrizine +Guaiphenesin	S.O. 892 (E)	

18.	Pseudoephedrine+Dextromethorphan +Cetirizine	S.O. 893 (E)	07th June 2018 09:30 am to 07:00pm
19.	Chlorpheniramine +Phenylephrine +Dextromethophan +Menthol	S.O. 894 (E)	
20.	Ambroxol + Terbutaline + Dextromethorphan	S.O. 895 (E)	
21.	Terbutaline +Bromhexine +Guaiphenesin+Dextromethorphan	S.O. 897 (E)	
22.	Dextromethorphan +Tripolidine +Phenylephirine	S.O. 898 (E)	
23.	Paracetamol +Dextromethorphan +Chlorpheniramine	S.O. 899 (E)	
24.	Diethylcarbamazine +Cetirizine +Ambroxol	S.O. 923 (E)	
25.	Cetirizine +Dextromethorphan +Bromhexine +Guaifenesin	S.O. 937 (E)	
26.	Paracetamol +Pheniramine	S.O. 1001 (E)	
27.	Bromhexine +Dextromethorphan	S.O. 1023 (E)	
28.	Dextrometharphan +Chlopheniramine +Ammonium Chloride +Sodium Citrate +Menthol	S.O. 1026 (E)	
29.	Albuterol + Etofylline + Bromhexine + Menthol	S.O. 1032 (E)	

6

Sr. No.	Name of FDC	S.O.Number	Date and time of hearing
1.	Dextromethorphan +Chlorpheniramine +Guaiphenesin	S.O. 896 (E)	08th June 2018 09:30 am to 07:00pm
2.	Pholcodine+Phenylephrine +Promethazine	S.O. 900 (E)	
3.	codeine + levocetirizine + menthol	S.O. 901 (E)	
4.	Cetirizine +Phenylephrine + Dextromethorphan + Menthol	S.O. 903 (E)	
5.	Paracetamol +Phenylephrine +Triprolidine	S.O. 905 (E)	
6.	Acetaminophen+Loratadine+ambroxol +Phenylephrine	S.O. 906 (E)	
7.	Cetirizine +Acetaminophen+Dextromethorphan +Phenyephrine +Zinc gluconate	S.O. 907 (E)	
8.	Diphenhydramine +Guaifenesin +Bromhexine +Ammonium Chloride +Menthol	S.O. 908 (E)	
9.	Chlopheniramine Maleate +Codeine syrup	S.O. 909 (E)	
10	Cetirizine +Dextromethorphan +Zinc Gluconate +Menthol	S.O. 910 (E)	
11	Paracetamol +Phenylephrine +Desloratadine+Zinc Gluconate +Ambroxol	S.O. 911 (E)	
12	levocetirizine + montelukast + acebrophylline	S.O. 912 (E)	
13	dextromethorphan + phenylephrine + ammonium chloride + menthol	S.O. 913 (E)	
14	Acrivastine+ Paracetamol + Caffeine + Phenylephrine	S.O. 915 (E)	
15	Dextromethorphan +Cetirizine	S.O. 917 (E)	
16	nimesulide + paracetamol + levocetirizine + phenylephrine + caffeine	S.O. 918 (E)	
17	Terbutaline +Ambroxol +Guaiphenesin+Zinc+Menthol	S.O. 919 (E)	
18	Codeine +Chlorpheniramine +Alcohol syrup	S.O. 920 (E)	

7

19.	Dextromethorphan +Phenylephrine +Guaifenesin+Triprolidine	S.O. 921 (E)	08th June 2018 09:30 am to 07:00pm
20.	Ammomium Chloride+Bromhexine +Dextromethorphan	S.O. 922 (E)	
21.	Ethylmorphine + Noscapine + Chlorpheniramine Maleate	S.O. 924 (E)	
22.	Cetirizine +Dextromethorphan +Ambroxol	S.O. 925 (E)	
23.	Bromhexine +Dextromethorphan +Ammonium Chloride +Menthol	S.O. 926 (E)	
24.	Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine	S.O. 927 (E)	
25.	Paracetamol +Phenylephrine +Chlorpheniramine +Zinc Gluconate	S.O. 928 (E)	
26.	Dextromethorphan +Phenylephrine +Cetirizine +Paracetamol +Caffeine	S.O. 929 (E)	
27.	Dextromethophan +Chlorpheniramine +Guaifenesin +Ammonium Chloride	S.O. 930 (E)	
28.	Levocetirizine +Dextromethorphan +Zinc	S.O. 931 (E)	
29.	Paracetamol +Phenylephrine +Levocetirizine +Caffeine	S.O. 932 (E)	
30.	Chlorpheniramine +Ammonium Chloride +Sodium Chloride	S.O. 933 (E)	
31.	Paracetamol +Dextromethorphan +Bromhexine +Phenylephrine +Diphenhydramine	S.O. 934 (E)	
32.	Salbutamol +Bromhexine +Guaiphenesin +Menthol	S.O. 935 (E)	
33.	Ketotifen +Cetirizine	S.O. 939 (E)	
34.	Ambroxol +Salbutamol +Theophylline	S.O. 942 (E)	
35.	Cetirizine +Nimesulide +Phenylephrine	S.O. 943 (E)	
36.	Acetaminophen+Guaifenesin+Dextromethorphan +Chlorpheniramine	S.O. 945 (E)	
37.	Cetirizine +Phenylephrine +Paracetamol+Ambroxol +Caffeine	S.O. 947 (E)	

38.	Guaifenesin+Dextromethorphan	S.O. 948 (E)	08th June 2018 09:30 am to 07:00pm
39.	Ketotifen +Levocetrizine	S.O. 951 (E)	
40.	Dextromethorphan +Phenylephirine +Guaifenesin	S.O. 955 (E)	

Sr. No.	Name of FDC	S.O.Number	Date and time of hearing
1.	Chlorpheniramine +Ammonium Chloride +Noscapine +Sodium Citrate	S.O. 936 (E)	09th June 2018 09:30 am to 07:00pm
2.	Diethyl Carbamazine +Chlorpheniramine +Guaifenesin	S.O. 938 (E)	
3.	Terbutaline +Bromhexine +Etofylline	S.O. 940 (E)	
4.	Ketotifen +Theophylline	S.O. 941 (E)	
5.	Chloropheniramine +Phenylephrine+Paracetamol+Zinc Gluconate	S.O. 944 (E)	
6.	Cetirizine +Dextromethorphan +Phenylephrine +Tulsi	S.O. 946 (E)	
7.	Levocetirizine +Paracetamol +Phenylephirine +Caffeine	S.O. 949 (E)	
8.	Caffeine +Paracetamol +Phenylephrine + Chlorpheniramine	S.O. 950 (E)	
9.	Paracetamol +Levocetirizine +Phenylephirine +Zinc Gluconate	S.O. 952 (E)	
10.	Dextromethorphan +Chlorpheniramine +Ammonium Chloride +Menthol	S.O. 958 (E)	
11.	Salbutamol +Aminophylline +Guaifenesin	S.O. 960 (E)	
12.	Chlorpheniramine +Terpin +Antimony Potassium Tartrate+Ammonium chloride+Sodium Citrate+Menthol	S.O. 966 (E)	
13.	Paracetamol +Pseudoephedrine +Cetirizine +Caffeine	S.O. 969 (E)	
14.	Chlorpheniramine +Ammonium Chloride +Menthol	S.O. 970 (E)	
15.	N-Acetyl Cysteine + Ambroxol + Phenylephrine + Levocetirizine	S.O. 971 (E)	
16.	Dextromethorphan +Phenylephrine +Tripolidine +Menthol	S.O. 972 (E)	

17.	Salbutamol +Cetirizine +Ambroxol	S.O. 973 (E)	09th June 2018 09:30 am to 07:00pm
18.	Dextromethorphan +Phenylephrine +Bromhexine +Guaifenesin+ Chlorpheniramine	S.O. 974 (E)	
19.	Nimesulide +Cetirizine +Phenylephrine	S.O. 975 (E)	
20.	Salbutamol+Bromhexine	S.O. 978 (E)	
21.	Guaifenesin+ Bromhexine + Chlorpheniramine + Paracetamol	S.O. 980 (E)	
22.	Chlorpheniramine +Ammonium Chloride +Chloroform +Menthol	S.O. 981 (E)	
23.	Salbutamol +Choline Theophylinate +Ambroxol	S.O. 982 (E)	
24.	Chlorpheniramine +Codeine phosphate +Menthol syrup	S.O. 983 (E)	
25.	Pseudoephedrine +Bromhexine	S.O. 984 (E)	
26.	Ambroxol + Salbutamol + Choline Theophyllinate + Menthol	S.O. 987 (E)	
27.	Chlorpheniramine +Vasaka +Tolubalsm +Ammonium Chloride +Sodium Citrate +Menthol	S.O. 989 (E)	
28.	Bromhexine +Cetrizine +Phenylephrine +Guaifenesin +Menthol	S.O. 990 (E)	
29.	Nimesulide + Levocetirizine	S.O.1851 (E)	
30.	Gemifloxacin + Ambroxol	S.O.1853 (E)	

Sr. No.	Name of FDC	S.O.Number	Date and time of hearing
1.	Paracetamol +Phenylephrine +Triprolidine +Caffeine	S.O. 953 (E)	11th June 2018 09:30 am to 04:00pm
2.	Caffeine +Paracetamol +Phenylephrine +Cetirizine	S.O. 954 (E)	
3.	Ambroxol + Levocetirizine + Phenylephrine + Guaiphenesin + Menthol	S.O. 956 (E)	
4.	Pseudoephedrine +Cetirizine	S.O. 957 (E)	
5.	Paracetamol +Caffeine +Phenylephrine +Chlorpheniramine	S.O. 959 (E)	
6.	Salbutamol +Thoephylline +Bromhexine	S.O. 961 (E)	
7.	Chlorpheniramine +Dextromethorphan +Guaifenesin +Phenylephrine	S.O. 962 (E)	
8.	Caffeine + Paracetamol+ Chlorpheniramine	S.O. 963 (E)	
9.	Ammonium Chloride+Dextromethophan+Cetirizine +Menthol	S.O. 964 (E)	
10.	Dextromethorphan +Paracetamol+Cetirizine +Phenylephrine	S.O. 965 (E)	

Sr. No.	Name of FDC	S.O. Number	Date and time of hearing
1.	Lignocaine+Clotrimazole+Ofloxacin+Beclomethasone	S.O. 773 (E)	12th June 2018
2.	Metformin+Atorvastatin	S.O. 785 (E)	09:30 am to 07:00pm
3.	Metformin 1000/1000/500/500mg +Pioglitazone 7.5/7.5/7.5/7.5mg + Glimepiride 1/2/1/2mg	S.O. 802 (E)	
4.	Gliclazide 80 mg + metformin 325 mg	S.O. 803 (E)	
5.	Voglibose+ Metformin + Chromium Picolinate	S.O. 804 (E)	
6.	Pioglitazone 7.5/7.5mg+Metformin 500/1000mg	S.O. 805 (E)	
7.	Glimepiride 1mg/2mg/3mg+Pioglitazone 15mg/15mg/15mg+Metformin 1000mg/1000mg/1000mg	S.O. 806 (E)	
8.	glimepiride 1mg/2mg+ pioglitazone 15mg/15mg + metformin 850mg/850mg	S.O. 807 (E)	
9.	Metformin 850mg+Pioglitazone 7.5 mg+Glimepiride 2mg	S.O. 808 (E)	
10.	Metformin 850mg+Pioglitazone 7.5 mg+Glimepiride 1mg	S.O. 809 (E)	
11.	Metformin 500mg/500mg+Gliclazide SR 30mg/60mg+Pioglitazone 7.5mg/7.5mg	S.O. 810 (E)	
12.	Voglibose+Pioglitazone+Metformin	S.O. 811 (E)	
13.	Metformin +bromocriptine	S.O. 812 (E)	
14.	Metformin +Glimepiride +Methylcobalamin	S.O. 813 (E)	
15.	Pioglitazone 30 mg+Metformin 500mg	S.O. 814 (E)	
16.	Metformin ER+Gliclazide MR+Voglibose	S.O. 818 (E)	
17.	Glibenclamide + Metformin (SR)+ Pioglitazone	S.O. 822 (E)	
18.	Chloramphenicol +Beclomethasone +Clomitrimazole +Lignocaine	S.O. 825 (E)	
19.	Ofloxacin +Clotrimazole +Betamethasone +Lignocaine	S.O. 828 (E)	
20.	Gentamicin Sulphate +Clotrimazole +Betamethasone +Lignocaine	S.O. 829 (E)	
21.	Clotrimazole +Beclomethasone +Ofloxacin +Lignocaine	S.O. 830 (E)	
22.	Becloemthasone +Clotrimazole+Chloramphenicol+Gentamycin +Lignocaine Ear drops	S.O. 831 (E)	
23.	Clotrimazole +Beclomethasone +Lignocaine +Ofloxacin +Acetic Acid +Sodium Methyl Paraben +Propyl Paraben	S.O. 1048 (E)	

13

Sr. No.	Name of FDC	S.O.Number	Date and time of hearing
1.	Glimepiride +Pioglitazone +Metformin	S.O. 815 (E)	13th June 2018 09:30 am to 07:00pm
2.	Glipizide 2.5mg+Metformin 400mg	S.O. 816 (E)	
3.	Pioglitazone 15mg+Metformin 850 mg	S.O. 817 (E)	
4.	Chromium Polynicotinate+Metformin Hydrochloride	S.O. 819 (E)	
5.	Metformin Hydrochlopride +Gliclazide +Pioglitazone +Chromium Polynicotinate	S.O. 820 (E)	
6.	Metformin +Gliclazide +Chromium Polynicotinate	S.O. 821 (E)	
7.	Metformin (sustainded release) 500mg+Pioglitazone 15 mg+Glimepride 3mg	S.O. 823 (E)	
8.	Metformin (SR) 500mg+Pioglitazone 5mg	S.O. 824 (E)	
9.	Thyroxine + Pyridoxine + Folic Acid	S.O. 857 (E)	
10.	Gliclazide 40mg+Metformin 400mg	S.O. 1029 (E)	
11.	levothyroxine pyridoxine+ nicotinamide	S.O. 1043 (E)	
12.	benfotiamine+ metformin	S.O. 1044 (E)	
13.	Thyroid +Thiamine + Riboflavin + Pyridoxine + Calcium Pantothenate + Tocopheryl Acetate +Nicotinamide	S.O. 1045 (E)	

Sr. No.	Name of FDC	S.O. Number	Date and time of hearing
1.	Amoxicillin +Dicloxacillin	S.O. 753 (E)	14th June 2018 09:30 am to 07:00pm
2.	Azithromycin+Cefixime	S.O. 752 (E)	
3.	Amoxicillin 250 mg+Potassium Clavulanate Diluted 62.5 mg	S.O. 754 (E)	
4.	Azithromycin + Levofloxacin	S.O. 755 (E)	
5.	Cefixime +Linezolid	S.O. 756 (E)	
6.	Amoxicillin +Cefixime +Potassium Clavulanic Acid	S.O. 757 (E)	
7.	Cefpodoxime Proxetil +Levofloxacin	S.O. 759 (E)	
8.	Levofloxacin +Ornidazole +Alpha Tocopherol Acetate	S.O. 761 (E)	
9.	Doxycycline +Serratiopeptidase	S.O. 765 (E)	
10.	Amoxycillin +Dicloxacillin +Serratiopeptidase	S.O. 771 (E)	
11.	Metronidazole +Tetracycline	S.O. 779 (E)	
12.	Cephalexin + Neomycin +Prednisolone	S.O. 780 (E)	
13.	Cetirizine Dihydrochloride +Diethyl Carbamazine	S.O. 792 (E)	
14.	cyproheptadine + thiamine	S.O. 835 (E)	
15.	Roxithromycin + Serratiopeptidase	S.O. 904 (E)	
16.	Neomycin + Doxycycline	S.O. 1008 (E)	
17.	Ammonium Citrate+Vitamin B 12+Folic Acid+Zinc Sulphate	S.O. 1042 (E)	
18.	Ascorbic Acid + Manadione Sodium Bisulphate+ Rutin + Dibasic Calcium Phosphate + Adrenochrome Mono Semicarbazone	S.O. 1046 (E)	

Sr. No.	Name of FDC	S.O.Number	Date and time of hearing
1.	Combikit of Azithromycin dihydrate, secnidazole and fluconazole	S.O. 760 (E)	15th June 2018 09:30 am to 05:00pm
2.	Azithromycin + ofloxacin	S.O. 763 (E)	
3.	Cefixime +levofloxacin	S.O. 766 (E)	
4.	Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets	S.O. 769 (E)	
5.	Ciprofloxacin +Phenazopyridine	S.O. 770 (E)	
6.	Azithromycin +Cefpodoxime	S.O. 772 (E)	
7.	Cafuroxime + Linezolid	S.O. 774 (E)	

Sr. No.	Name of FDC	S.O. Number	Date and time of hearing
1.	Aceclofenac + Paracetamol + Rabeprazole	S.O. 705 (E)	18th June 2018 09:30 am to 07:00pm
2.	Nimesulide + Diclofenac	S.O. 706 (E)	
3.	Nimesulide +Tizanidine	S.O. 708 (E)	
4.	Diclofenac + Tramadol + Chlorzoxazone	S.O. 710 (E)	
5.	Nimesulide +Paracetamol dispesible tablets	S.O. 712 (E)	
6.	Diclofenac +Tramadol +Paracetamol	S.O. 714 (E)	
7.	Naproxen+Paracetamol	S.O. 716 (E)	
8.	Nimesulide + serratiopeptidase	S.O. 717 (E)	
9.	Nimesulide + Pitofenone + Fenpiverinium + benzyl alcohol	S.O. 719 (E)	
10.	Omeprazole + Paracetamol + Diclofenac	S.O. 720 (E)	
11.	Nimesulide + Paracetamol injection	S.O. 721 (E)	
12.	Diclofenac +Zinc Carnosine	S.O. 724 (E)	
13.	Diclofenac + paracetamol+ chlorpheniramine maleate + magnesium trisillicate	S.O. 725 (E)	
14.	Phenylbutazone+Sodium Salicylate	S.O. 727 (E)	
15.	Lornoxicam+Paracetamol+Trypsin	S.O. 728 (E)	
16.	Heparin +Diclofenac	S.O. 731 (E)	
17.	Glucosamine +Methyl Sulfonyl Methane+Vitamin D3 + Manganese + Boron+ Copper +Zinc	S.O. 732 (E)	

17

18.	Paracetamol +Tapentadol	S.O. 733 (E)	18th June 2018 09:30 am to 07:00pm
19.	Benzoxonium Chloride+Lidocaine	S.O. 735 (E)	
20.	Lornoxicam +Paracetamol +Tramadol	S.O. 736 (E)	
21.	Lornoxicam +Paracetamol +Serratiopeptidase	S.O. 737 (E)	
22.	Diclofenac +Paracetamol +Magnesium trisilicate	S.O. 738 (E)	
23.	Nimesulide +Paracetamol suspension	S.O. 743 (E)	
24.	Paracetamol + disodium Hydrogen Citrate + Caffeine	S.O. 746 (E)	
25.	Disodium Hydrogen citrate +Paracetamol	S.O. 748 (E)	
26.	Diclofenac + Paracetamol injection	S.O. 751 (E)	
27.	Menthol +Anesthetic Ether	S.O. 1025 (E)	

Sr. No.	Name of FDC	S.O. Number	Date and time of hearing
1.	Dicyclomine +Paracetamol +Domperidone	S.O. 711 (E)	19th June 2018 09:30 am to 04:30pm
2.	Diclofenac + paracetamol + chlorzoxazone + famotidine	S.O. 715 (E)	
3.	Paracetamol +Diclofenac +Famotidine	S.O. 718 (E)	
4.	Paracetamol +Mefenamic Acid +Ranitidine +Dicyclomine	S.O. 729 (E)	
5.	Nimesulide + Dicyclomine	S.O. 730 (E)	
6.	Paracetamol +Domperidone +Caffeine	S.O. 739 (E)	
7.	Combikit of 3 tablets of Serratiopeptidase (enteric coated 20000 units) + Diclofenac Potassium & 2 tablets of Doxycycline	S.O. 742 (E)	
8.	Aceclofenac +Paracetamol +Famotidine	S.O. 744 (E)	
9.	Aceclofenac + Zinc Carnosine	S.O. 745 (E)	
10.	Paracetamol + DL Methionine	S.O. 747 (E)	
11.	Aceclofenac (SR) + Paracetamol	S.O. 750 (E)	
12.	Ofloxacin +Nitazoxanide	S.O. 758 (E)	
13.	Ofloxacin +Metronidazole +Zinc Acetate	S.O. 767 (E)	
14.	Diphenoxylate +Atropine +Furazolidone	S.O. 768 (E)	
15.	Ofloxacin +Ornidazole +Zinc bisglycinate	S.O. 775 (E)	
16.	Flunarizine + Paracetamole+ Domperidone	S.O. 832 (E)	
17.	Ranitidine +Magaldrate	S.O. 846 (E)	

18.	Norfloxacin+ Metronidazole + zinc Acetate	S.O. 847 (E)	19th June 2018 09:30 am to 04:30pm
19.	Zinc Carnosine+Oxetacaine	S.O. 848 (E)	
20.	Oxetacaine +Magaldrate +Famotidine	S.O. 849 (E)	
21.	Zinc Carnosine+MagnesiumHydroxide +Dried Aluminium Hydroxide +Simethicone	S.O. 851 (E)	
22.	Zinc Carnosine+Sucralfate	S.O. 852 (E)	
23.	Levocetirizine +Ranitidine	S.O. 885 (E)	
24.	Ergotamine Tartrate +Belladona dry extract +Caffeine +Paracetamol	S.O. 1027 (E)	
25.	Paracetamol +Propyphenazone +Caffeine	S.O. 1036 (E)	
26.	Etodolac + Paracetamol	S.O.1855 (E)	
27.	Glucosamine + Ibuprofen	S.O.1854 (E)	

20

Sr. No.	Name of FDC	S.O.Number	Date and time of hearing
1.	Nimorazole+Ofloxacin	S.O. 762 (E)	20th June 2018 09:30 am to 04:00pm
2.	amoxycillin + tinidazole	S.O. 764 (E)	
3.	Metronidazole +Norfloxacin	S.O. 776 (E)	
4.	Doxylamine +Pyridoxine +Mefenamic Acid+Paracetamol	S.O. 793 (E)	
5.	Drotaverine + Clidinium + Chlordiazepoxide	S.O. 794 (E)	
6.	Ursodeoxycholic Acid + Silymarine	S.O. 801 (E)	
7.	Rabeprazole +Zinc carnosine	S.O. 833 (E)	
8.	magaldrate + famotidine + simethicone	S.O. 834 (E)	
9.	Magaldrate +Ranitidine +Pancreatin +Domperidone	S.O. 836 (E)	
10.	Ranitidine +Magaldrate +simethicone	S.O. 837 (E)	
11.	magaldrate + papain+ fungul diastase + simethicone	S.O. 838 (E)	
12.	Rabeprazole + zinc + domperidone	S.O. 839 (E)	
13.	Famotidine + oxytacaine + Magaldrate	S.O. 840 (E)	
14.	Ranitidine+Domperidone+Semithicone	S.O. 841 (E)	
15.	Alginic Acid+Sodium Bicarbonate+Dried Aluminium Hydroxide+Magnesium Hydroxide	S.O. 842 (E)	
16.	Clidinium +Paracetamol +Dicyclomine +Activated Dimethicone	S.O. 843 (E)	
17.	Furazolidone +Metronidazole +Loperamide	S.O. 844 (E)	
18.	Rabeprazole +Diclofenac +Paracetamol	S.O. 845 (E)	

19.	Pantoprazole (as Enteric Coated Tablet)+Zinc Carnosine (as Film Coated Tablets)	S.O. 850 (E)	20th June 2018 09:30 am to 04:00pm
20.	Mebeverine Hydrochloride & Inner HPMC capsule (Streptococcus Faecalis +Clostridium butyricum +Bacillus mesentricus+Lactic Acid Bacillus)	S.O. 853 (E)	
21.	Oflaxacin + Ornidazole suspension	S.O. 1031 (E)	
22.	Dried Alumnium Hydroxide Gel +Propantheline Bromide +Diazepam	S.O. 1038 (E)	
23.	Ofloxacin + Ornidazole injection	S.O.1852 (E)	

Sr. No.	Name of FDC	S.O.Number	Date and time of hearing
1.	Ciprofloxacin +Fluticasone +Clotrimazole +Neomycin	S.O. 778 (E)	21st June 2018 09:30 am to 07:00pm
2.	cilnidipine + metroprolol succinate + metroprolol tartrate	S.O. 782 (E)	
3.	atorvastatin + vitamin D3 + folic acid + vitamin B12 + pyridoxine	S.O. 784 (E)	
4.	Clindamycin+Telmisartan	S.O. 786 (E)	
5.	Olmesartan+Hydrochlorothiazide +Chlorthalidone	S.O. 787 (E)	
6.	Clotrimazole + Ofloxaxin + Lignocaine + glycerine and propylene glycol	S.O. 826 (E)	
7.	Chloramphennicol+Lignocain+Beta methasone+Clotrimazole+Ofloxaci n+Antipyrine	S.O. 827 (E)	
8.	Gentamycin+Dexamethasone+Chlo ramphenicol+Tobramycin+Ofloxaci n	S.O. 858 (E)	
9.	Naphazoline +carboxy Methyl cellulose +Menthol +Camphor +Phenylephrine	S.O. 916 (E)	
10.	Naphazoline +Chlorpheniramine +Zinc Sulphate +Boric Acid Ip+Sodium chloride +chlorobutol	S.O. 976 (E)	
11.	Betamethasone +Fusidic Acid+Gentamycin +Tolnaftate+Iodochlorhydroxyquin oline(ICHQ)	S.O. 1002 (E)	
12.	Clobetasol +Ofloxacin+Miconazole +Zinc Sulphate	S.O. 1003 (E)	
13.	Clobetasole +Gentamicin +Miconazole +Zinc Sulphate	S.O. 1004 (E)	
14.	Permethrin + Cetrimide + Menthol	S.O. 1006 (E)	
15.	beclomethasone + clotimazole + neomycin + iodochlorohydroxyquinone	S.O. 1007 (E)	
16.	Ciprofloxacin + Fluocinolone + Clotrimazole + Neomycin + Chlorocresol	S.O. 1009 (E)	

17.	Clobetasol + Ofloxacin + Ketoconazole + Zinc Sulphate	S.O. 1010 (E)	21st June 2018 09:30 am to 07:00pm
18.	Betamethasone +Gentamicin +Tolnaftate +Iodochlorhydroxyquinoline	S.O. 1011 (E)	
19.	Clobetasol +Gentamicin +Tolnaftate +Idochlorhydroxyquinone +Ketoconazole	S.O. 1012 (E)	
20.	Allantoin+Dimethieone+Urea+Propylene+Glycerin+Liquid paraffin	S.O. 1013 (E)	
21.	Acriflavine +Thymol+Cetrimide	S.O. 1014 (E)	
22.	Betamethasone +Neomycin +Tolnaftate +Iodo Chloro Hydroxy Quinoline +Cholorocresol	S.O. 1015 (E)	
23.	clobetasol +Neomycin +Miconazole +Clotrimazole	S.O. 1016 (E)	
24.	Ketoconazole+Tea Tree oil+Allantion+zinc Oxide+Aloe Vera+Jojoba oil+Lavander oil+Soap noodles	S.O. 1017 (E)	
25.	Clobetasol +Ofloxacin +Ornidazole +Terbinafine	S.O. 1018 (E)	
26.	Clobetasol +Neomycin +Miconazole +Zinc Sulphate	S.O. 1019 (E)	
27.	Beclomethasone +Neomycin +Tolnaftate +Iodochlorhydroxyquinoline +Chlorocresol	S.O. 1020 (E)	
28.	Betamethasone +Gentamycin +Zinc Sulphate +Clotrimazole +Chlorocresol	S.O. 1021 (E)	
29.	Borax +Boric acid +Naphazoline +Menthol +Camphor + methyl hydroxy benzoate	S.O. 1022 (E)	
30.	Beclomethasone +Clotrimazole+Gentamicin+IodoChlorhydroxyquinoline	S.O. 1040 (E)	
31.	Telmisartan + Metformin	S.O. 1041 (E)	

24

Sr. No.	Name of FDC	S.O. Number	Date and time of hearing
1.	Tamsulosin + diclofenac	S.O. 722 (E)	22nd June 2018 09:30 am to 07:00pm
2.	Tranexamic Acid + Proanthocyanidin	S.O. 734 (E)	
3.	Paracetamol +Prochlorperazine Maleate	S.O. 741 (E)	
4.	L-Arginine +Sildenafil	S.O. 783 (E)	
5.	L-5-Methylterahydrofolate calcium + Escitalopram	S.O. 788 (E)	
6.	Paracetamol +Promethazine	S.O. 790 (E)	
7.	Betahistine +Ginkgo Biloba Extract+Vinpocetine+Piracetam	S.O. 791 (E)	
8.	Imipramine + Diazepam	S.O. 795 (E)	
9.	Flupentixol +Escitalopram	S.O. 796 (E)	
10.	Paracetamol + Prochloperazine	S.O. 797 (E)	
11.	Gabapentin +Mecobalamin +Pyridoxine +Thiamine	S.O. 798 (E)	
12.	Imipramine +Chlordiazepoxide +Trifluoperazine +Trihexyphenidyl	S.O. 799 (E)	
13.	Chlorpromazine +Trihexyphenidyl	S.O. 800 (E)	
14.	Clindamycin +Clotrimazole +Lactic Acid Bacillus	S.O. 854 (E)	
15.	Sildenafil +Estradiol Valerate	S.O. 855 (E)	
16.	Clomifene Citrate +Ubidecarenone +Zinc +Folic Acid +Methylcobalamin +Pyridoxine +Lycopene +Selenium+Levocarnitine Tartrate+L-Arginine	S.O. 856 (E)	
17.	Phenytoin +Phenobarbitone sodium	S.O. 1028 (E)	

683

File No. 4-01/2013-DC (Misc. 13-Part 1)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:

NOTICE 24 MAY 2018

Subject: Consideration of the directions of the Hon'ble Supreme Court of India in the case of 344 FDCs + 05 FDCs prohibited vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855 (E) dated 08.06.2017 and constitution of a sub-committee for having a relook in these cases-regarding.

This is in continuation to this office notice 4-01/2013-DC (Misc. 13-Part 1) dated 20.04.2018 on the subject cited above whereby all the petitioners/appellants including AIDAN were requested to submit the information in the prescribed format as per Annexure A/Annexure D by 02nd May 2018 till 5:00 P.M. for further action in compliance to the directions of the Hon'ble Supreme Court.

In this regard, various representations were received requesting for further extending the timeline for submission of the information. The issue was considered by DTAB Sub Committee and it has been decided that petitioners/appellants including AIDAN may be permitted to submit the information in the prescribed format by 4th June 2018 till 5:00 p.m.

In view of above, all the petitioners/appellants including AIDAN to note that date for the submission of information in the prescribed format is extended upto 04.06.2018 till 5:00 p.m.

(Sanjeev Kumar)
Convener
Sub-Committee of DTAB

Copy to:

1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB.
2. All India Drugs Action Network
3. Website of CDSCO for information and necessary action of AIDAN for complying the hearing and subsequent report submission process.
4. Indian Drugs Manufacturing Associations (IDMA)/Federation of Pharma Enterpreneurs (FOPE)

File No. 4-01/2013-DC (Misc. 13-PSC-Part-I)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 24 MAY 2018

PUBLIC NOTICE

Subject: Meeting of DTAB Sub Committee for examining the 344 FDCs + 05 FDCs and to provide hearing to the petitioners/appellants including AIDAN-regarding.

As you are aware that the Sub-Committee of DTAB has been constituted under the chair personship of Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai to examine the banned 344 FDCs + 05 FDCs with S. O. No. 705 (E) to 1048 (E) dated 10.03.2016 and S. O. 1851 (E) to 1855 (E) dated 08.06.2017 respectively.

Accordingly, vide public notice dated 12.03.2018 published on website of CDSCO, it was requested to submit the information in the prescribed format in hard as well as in soft copy.

Now, in compliance to the directions of Hon'ble Supreme Court of India vide dated 15.12.2017, it has been proposed to give hearing to all the petitioners/appellants including AIDAN for deliberation by the Sub-committee.

Accordingly, Sub-Committee invites the concerned applicants for hearing w.e.f. 05.06.2018. As regard to hearing for the particular FDC, the schedule of hearing will be published time to time on CDSCO website i.e. www.cdsco.nic.in. Accordingly, all concerned are requested to regularly visit the CDSCO website and avail the opportunity of hearing on the given date. It may be noted that no separate letter will be sent for the hearing schedule.

This is for information of all concerned.

(Sanjeev Kumar)
DDC(I), CDSCO (HQ) &
Convener, Sub-Committee of DTAB

Copy for necessary action to:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson)
2. Indian Drugs Manufacturing Associations IDMA/FOPE/CIPI/IPA- with the request to communicate it to your members and publicize it widely so that all concerned can avail this opportunity.
3. All India Drug Action Network
4. Website of CDSCO for information and necessary action of all petitioners/appellants including AIDAN and stakeholders involved in the case for compliance in hearing.

685

File No. 4-01/2013-DC (Misc. 13-Part 1)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:

NOTICE

Subject: Consideration of the directions of the Hon'ble Supreme Court of India in the case of 344 FDCs + 05 FDCs prohibited vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855 (E) dated 08.06.2017 and constitution of a sub-committee for having a relook in these cases-regarding.

20 APR 2018

This is in continuation to this office notice 4-01/2013-DC (Misc. 13-Part 1) on the subject cited above whereby all the petitioners/appellants including AIDAN were requested to submit the information in the prescribed format as per Annexure A/Annexure D by 7th April 2018 till 5:00 P.M. for further action in compliance to the directions of the Hon'ble Supreme Court.

In this regard, various representations were received requesting for extending the timeline for submission of the information. The issue was considered by sub-committee in its meeting held on 20.04.2018 and it has been decided that petitioners/appellants including AIDAN may be permitted to submit the information in the prescribed format by 2nd May 2018 till 5:00 p.m.

In view of above, all the petitioners/appellants including AIDAN to note that date for the submission of information in the prescribed format is extended upto 02.05.2018 till 5:00 p.m.

(Sanjeev Kumar)
Convener
Sub-Committee of DTAB

Copy to:
1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB.
2. All India Drugs Action Network
3. Website of CDSCO for information and necessary action of AIDAN for complying the hearing and subsequent report submission process.
4. Indian Drugs Manufacturing Associations (IDMA)/Federation of Pharma Enterpreneurs (FOPE)

F. No- 4-01/2013-DC(Misc 13-Part1)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan Kotla Road,
New Delhi

Dated: 12 MAR 2018

NOTICE

Subject: Consideration of the directions of the Hon'ble Supreme Court of India in the case of 344 FDCs + 05 FDCs prohibited vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855(E) dated 08.06.2017 and constitution of a sub-committee for having a relook in these cases- Regarding.

In the 78th meeting of the Drugs Technical Advisory Board (DTAB) held on 12th February, 2018 under the Chairmanship of the Director General of Health Services, the DTAB deliberated the directions of the Hon'ble Supreme Court of India dated 15.12.2017 in regard to the notifications issued by the Govt. of India prohibiting 344 FDCs +05 FDCs vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855(E) dated 08.06.2017 respectively.

The Hon'ble Supreme Court in its order dated 15.12.2017 had inter alia directed that these cases should go to the DTAB and/or its sub-committee formed by the DTAB for the purpose of having a relook into these cases. The committee will not only hear the petitioners/appellants before but they also hear submissions from All India Drugs Action Network (AIDAN). The DTAB/sub-committee set up for the purpose will deliberate on the parameters set out in section 26A of the Drugs & Cosmetics Act.

Accordingly, a sub-committee has been constituted under the Chairmanship of Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, ICMR, Mumbai, to examine the banned 344 FDCs + 5 FDCs vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855(E) dated 08.06.2017 respectively.

In this regard, a meeting of the sub-committee of DTAB took place on 1st March 2018. The committee has desired and requested that AIDAN may submit the information in the prescribed format as per **Annexure 'D'** which is enclosed herewith for further action in compliance to the directions of the Hon'ble Supreme Court.

Accordingly, All India Drugs Action Network is hereby requested to submit the information in the prescribed format in hard copy as well as in soft copy (i.e. in C.D. form) to this office latest by the 7th April 2018 till 5:00 P.M. to fulfil the DTAB Sub-Committee proceedings as per Hon'ble Supreme Court order.

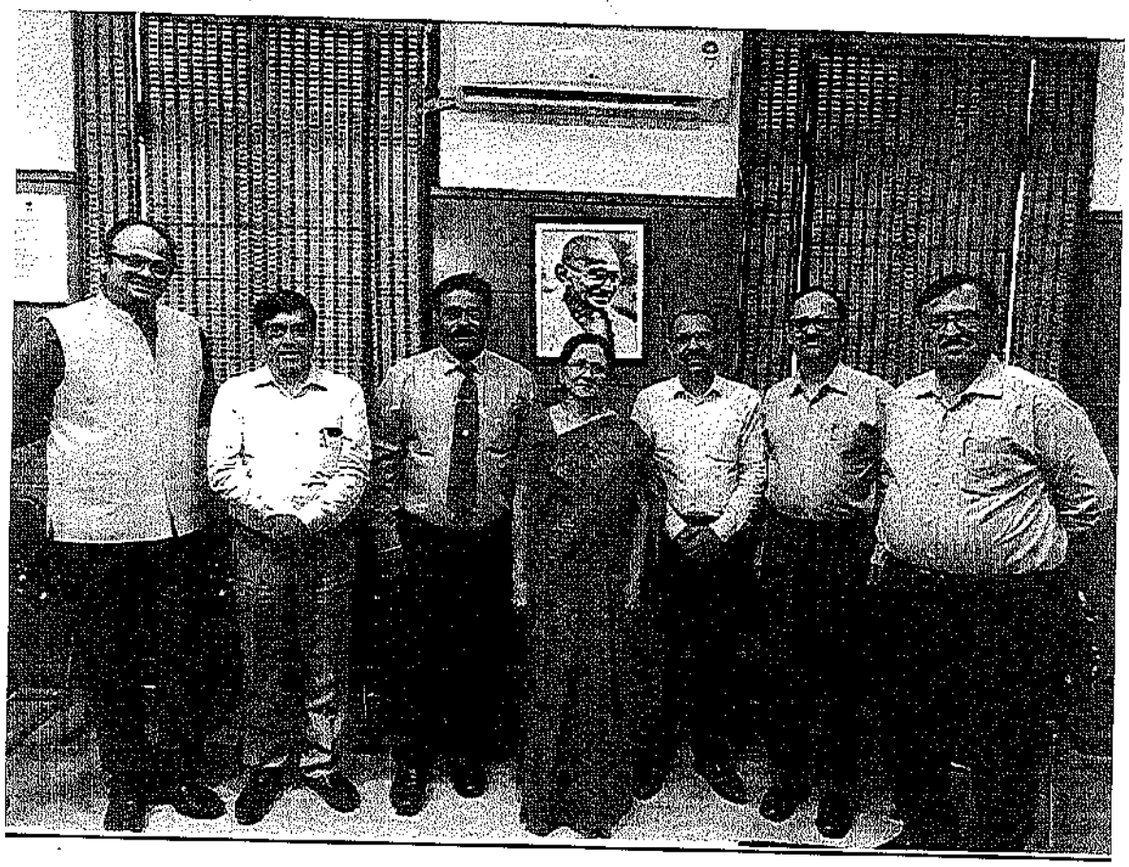
(Sanjeev Kumar)
Convener
Sub-Committee of DTAB

Copy to:

1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB
2. All India Drugs Action Network
4. Website of CDSCO for information and necessary action of AIDAN for complying the hearing and subsequent report submission process.

687

Group Photograph of the Subcommittee



Brief note about the Subcommittee members

Dr. Nilima Kshirsagar, National Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson).

Dr. Nilima Kshirsagar MD. PhD, FNAMS(India) FNAS (India) FRCP (UK) FACCP (USA) studied at the GS Medical college KEM Hospital, Mumbai and as Searle Research Fellow at St. Bartholomew's hospital UK. She was appointed as Professor & Head, Clinical Pharmacology, Dean at TN Medical College, BYL Hospital, GS Medical college KEM hospital, and ESI PGIMSR Mumbai, later as Director, Medical Education and Research, and Acting Vice Chancellor MUHS, Nasik. She was Member Governing Council, Chairperson, Academic Council of AIIMS Delhi. She received several University, National and International awards e.g. Mayor of Mumbai award thrice, Vasvik Award for Industrial research, BC Roy Award and now Nathaniel T Kwit award of American College of Clinical Pharmacology. She has over 200 publications including in Lancet, BMJ, Lancet global health, delivered lectures and orations and has carried out drug development and clinical trials with funding from WHO, DBT, ICMR, NIH.

She is Member of WHO committees on Medicines safety (ACSoMP), Drug Statistics methodology, Scientific Advisory committee, DNDi (Drugs for Neglected disease initiative) Secretary General Clinical Pharmacology Section International Union of Basic and Clinical Pharmacology (IUPHAR), Member IND committee, Chairperson PvPi training panel, Chairperson DSMC bedaquiline, Chairperson PRC Pharmacology ICMR, Govt. of India, Member Board of Directors Foundation for Disease elimination and Control.

Dr. Nirmala N. Rege is a Professor and Head of Department of Pharmacology and Therapeutics at Seth GS Medical College and KEM Hospital, Mumbai.

- MD (Pharmacology), DNB (Clinical Pharmacology) and PhD (Pharmacology). Training in 'Teaching Rational Pharmacotherapy' at University of Groningen, Groningen, Netherlands.
- Recognised University teacher for MD and PhD (Pharmacology), and MSc and PhD (Applied Biology)
- Expert in evaluation of modern and Ayurvedic drugs for their efficacy and safety through GCP-compliant clinical trials.
- Investigator for projects sponsored by various Government of India Organizations viz. Dept. of AYUSH, NMITLI, CSIR, Dept. of Science & Technology (DST), Indian Council of Medical Research and Dept. of Biotechnology

- Experience of reviewing grant proposals submitted to National agencies, and research articles for peer-reviewed journals, scrutinizing projects for ethical and scientific considerations and monitoring clinical trials for safety (as a member of DSMB).
- Recipient of more than 40 awards for her research in the field of pharmacology and Ayurveda and has 110 publications and 2 textbooks viz. Satoskar-Bhandarkar's 'Pharmacology and Pharmacotherapeutics' and 'Practical Pharmacology for Medical Students'.
- Convenor of MCI Regional Centre for faculty development and Co-director of Regional institute of Foundation of Advances in Medical Education and Research (FAIMER), USA, President, South Asia College , American College of Clinical Pharmacology (SAC-ACCP).

Sh. Omprakash S. Sadhwani, Former Joint Commissioner & Drugs Controller, Maharashtra

Member of DTAB

- Expert in Detection and investigation of cases.
- Faculty on investigation skills
- Wide expertise in policy making for state FDA
- Having 30 years expertise in enforcement of Drug Laws.
- Awarded best Drugs Control officer by Govt. of Maharashtra.
- All India Drug Control Officers Association Best Drug Control Officer India-2010

Dr. R N Tandon (Honorary Secretary General, IMA)

Dr R N Tandon who hails from Lucknow has done MBBS and M.S. from Maharani Laxmibai Medical College, Jhansi.

He has worked at the Sufderjung hospital, St. Stephen Hospital, Jessa Ram Hospital, Jaipur Golden Hospital and Vinayak Hospital in New Delhi as Surgeon. With his great dedication and efforts, a Department of Surgery was started in Action Balaji hospital in New Delhi.

In 1988, he joined the well known Karol Bagh Medical Society as an activist and Joint Secretary. He has been associated with IMA for the last 28 years. He has served the Karol Bagh Branch as its Joint Secretary, Finance Secretary, Secretary and President as well.

He has held various posts in almost all the wings of IMA HQs like IMA CGP, IMA AMS. In IMA HQs he has held various posts like Asstt. Secretary, Joint Secretary, Finance Secretary and other important posts and since 28th December 2016 he is Honorary Secretary General of Indian Medical Association which is the largest Association of doctors in the world.

Under his able guidance, various projects like Treatment of Diarrhea, ORS-Zinc, Breastfeeding, Infant mortality and Child Sexual Abuse were undertaken.

He introduced unique way of community Service when he was Secretary/President of IMA Karol Bagh Branch and mass deworming was started way back in 2001 in selected locality of Karol Bagh.

He is recipient of many appreciation Awards from Delhi State and received IMA Diamond Jubilee IDPL Oration Award and **IMA Dr. B. R. Ramasubramanian Oration Award for Best Paper Presented at the IMA National Conference.**

He has held various important posts in Delhi Medical Association.

Dr. Agam Vora-MD Chest CTB (Member)

- Asst. Hon Chest Physician-Dr RN Cooper Municipal General Hospital
- Additional board member-Journal of association and physician Indian chest (American college and chest physician)-Indian Edition
- Fellow, Geriatric society of India, Indian College of Physician, National college of Chest Physician, American College and Chest Physician.
- Trustee, Malad Medical Association
- General Secretary, Academy of Advanced Medical Education
- Recipient of many awards and Young Scientist award by Tuberculosis Association of India.
- Active member of Indian Medical Association
- Delivered more than 500 Guest lectures
- Organized more than 30 National Lectures and International Conference meetings.
- Ex-Associate Professor., Department of Chest and TB at K.S. Somaiya Medical College
- Teaching experience of 8 more than 15 years.

Dr. T.V. Narayana, President Indian Pharmaceutical Association (IPA) (Member)
General Secretary, Indian Pharmaceutical Congress Association (IPCA).

- M. Pharma, Ph. D in Pharmacology
- Having 30 years of experience in teaching, administration and research in Pharmacy
- President of Indian Pharmaceutical Association (A National Professional body of Pharmacists engaged in various faces of profession of Pharmacy)
- General Secretary of Indian Pharmaceuticals Congress Association.

Dr. Sandeep B Bavdekar retired as the Professor and Head, Department of Pediatrics, Topiwala National Medical College and BYL Nair Charitable Hospital, Mumbai.
He completed his under-graduate (MBBS) and post-graduate degree (MD- Pediatrics) education from LTM Medical College, Mumbai. He has been a medical teacher for MBBS, MD (Pediatrics) and DNB (Pediatrics) courses for over 30 years. He has been a keen researcher having been an investigator associated with 85 research projects and presented as many research papers at various international and national conferences. He was awarded the prestigious ST Achar Endowment Award in 2000. He has been a renowned faculty for conferences and workshops related to Pediatrics and Pediatric specialties, research methodology, research ethics and Medical education technology. He has also served as a Member on five Institutional Ethics Committees. He has organized over 40 international, national and regional conferences and workshops. He has published 185 articles in peer-reviewed national and international journals and has been an Editor of Journal of Postgraduate Medicine (JPGM) and Pediatric Clinics of India .Dr. Bavdekar has authored 75 chapters in books and textbooks. He has been associated with and has organized several educational and training programs for the Indian Academy of Pediatrics. He was awarded the Fellowship of Indian Academy of Pediatrics (FIAP).

Rao V. S. V. Vadlamudi, Ph. D.,
President, Commonwealth Pharmacists Association (CPA)
Immediate Past President, Indian Pharmaceutical Association

B. Pharm- 1973, M. Pharm (Pharm. Chem.)- 1976;
Andhra University, Visakhapatnam, India
M. Sc.- 1980, Ph. D. (Pharmacology and Toxicology)- 1983;
The University of British Columbia, Vancouver, B.C., Canada

In 1984, Rao Vadlamudi started his career at UDCT, Matunga, Mumbai, and during a career spanning 34 year, he worked in academia as well as in the Pharma industry in various capacities.

Academic positions held by Dr. Vadlamudi include Reader in Pharmacology, UDCT, Professor in Pharmacology, Bombay College of Pharmacy (BCP), first ever Director of BCP, Director of St. Peter's Institute of Pharmaceutical Sciences, Warangal and Adjunct Professor, Acharya & B. M. Reddy College of Pharmacy, Bengaluru.

His industry career began in 1990 in the Hoechst Research Centre as Head, Pharmacology. He was Head, Pharmacology in the Piramal Research Centre; VP, Discovery Biology in Suven Life Sciences; VP and Principal Fellow, Nektar Therapeutics India Limited, and Sr. VP -Life Sciences at Vimta Labs Ltd, Hyd.

He was the Editor of Indian Journal of Pharmaceutical Sciences, the official scientific publication of the Indian Pharmaceutical Association (IPA) from 1996-2014. He served as the President of the Indian Pharmaceutical Association for two terms 2014-16 and 2016-18 and during this period he was a member of the Drug Technical Advisory Board (DTAB) of the Ministry of Health and Family Welfare, Govt of India. Currently he is the President of the Commonwealth Pharmacists Association (CPA) and a member of the Governing Body of the Life Sciences Sector Skill Development Council (LSSSDC) of India.

He received the Fellowship of the Indian Pharmaceutical Association in 2000; the Dr. B. N. Ghosh Memorial Oration Award of the Indian Pharmacological Society in 2005, the Prof. M. L. Khorana Memorial Lecture Award of IPA in 2009, the Eminent Pharmacist award of IPA in 2013, the IPA President's Special Oration award in 2014 and the Fellowship of the Association of Biotechnology and Pharmacy in Dec 2014.