

F.No. 4-01/2013-DC (Misc. 13-PSC -Pt-Meeting)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan,
Kotla Road, New Delhi

Dated: **12 AUG 2014**

To

1. Dr. Y.K.GUPTA, Prof. & Head, Dept. of Pharmacology, All India Institute of Medical Sciences (AIIMS), Main Hospital, Ansari Nagar, In front of Safdarjung Hospital, New Delhi - 110 029.
2. Dr. Shashank V. Parulekar, Prof. & Head, Dept. of Obstetrics & Gynaecology, Seth GS Medical College & KEM Hospital, Parel, Mumbai-400012.
3. Dr. Lakhbir Dhaliwal, Prof & Head, Dept. of Obstetrics and Gynaecology, PGIMER, Chandigarh.
4. Dr. S. N. Bhattacharya, Prof & Head, Dept. of Dermatology, UCMS, New Delhi.
5. Dr. Asit Mittal, Professor, Dept. of Dermatology, Venereology & Leprosy, R N T Medical College, Udaipur, Rajasthan - 313001.

Subject:- Fifth Meeting of the Expert Committee on 22.08.2014 at 11:00 a.m. to 6:00 p.m. in the Conference Room, 1st floor, FDA Bhawan, Kotla Road, Near National Bal Bhawan, New Delhi-110002, to examine the matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG(1) – regarding.

Sir,

Reference is invited to this Directorate's Office Memorandum No. 4-01/2013-DC (Misc13-PSC) dated 03.02.2014 on the subject cited above.

This office in the following proposals for approval of Fixed Dose Combinations seeks your expert opinion of Expert Committee as to whether based on the data submitted by the firm, these proposals can be approved.

S.No.	Name of firm/ Institute	Drug
1	1.Laurochem labs	1.Octinoxate 7.5 % w/w + avobenzone 3.0 % w/w + oxybenzone 3.0 % w/w + zinc oxide 2.0 % w/w topical lotion
	2.Rexcin Pharmaceuticals	2.Octinoxate USP 7.5%w/w +Avobenzone USP 2%w/w +Oxybenzone USP 3%w/w +Processed Zinc Oxide 2%w/w Topical Gel
2	Universal Twin Labs	Acicflavine HCl 0.12gm +Thymol 5.00mg +Cetrimide 0.50gm Cream
3	Psychotropies India Ltd	Allantoin BP 0.25%w/w +Vitamin-E Acetate 0.25w/w +Tea tree oil 0.50%w/w Medicated Soap
4	Psychotropies India Ltd	Allantoin BP 0.20%w/w +Vitamin-E Acetate 0.25%w/w +Tea tree oil 0.25%w/w +Titanium Dioxide IP 0.50%w/w Medicated Soap
5	Yash Medicare	Allantoin 0.2%w/w +Dimethicone 1.0%w/w +Urea 10.0%w/w +Propylene 5.0%w/w +Glycerin 5.0%w/w +Liquid paraffin 8.0%w/w Cream
6	1.Psychotropies India	1.Aloe IP 4%+Vitamin E Acetate IP 0.50% w/w Soap
	2.East West Pharma	2.Aloe 10%w/v +Vitamin E Acetate 0.5%w/v Lotion

7	1. Gelnova Laboratories 2. Sun Industries Pharmaceuticals 3. Akums drugs & pharmaceuticals limited 4. Gelnova laboratories 5. Zuventus Healthcare 6. Glenmark Pharmaceuticals	1. Clindamycin Phosphate BP eq. to Clinda + Clotrimazole IP 200mg Vaginal suppository 2. Clotrimazole 200mg + Clindamycin 100mg suppository 3. clindamycin phosphate 100 mg + clotrimazole 200 mg capsu 4. clindamycin phosphate 100 mg + clotrimazole 100 mg soft gelatin vaginal suppository 5. clotrimazole 200 mg + clindamycin 100 mg Extended Release vaginal tablet 6. Clotrimazole IP 2%w/w + Clindamycin Phosphate 2%w/w + Benzyl Alcohol IP 2%w/w Gel
8	Akums Drugs & Pharmaceuticals Ltd	Clindamycin Phosphate BP Eq. to Clindamycin 100mg + Clotrimazole IP 200mg + Lactic Acid Bacillus 1.5 Billion Spores Soft Gelatin vaginal
9	Synokem Pharmaceuticals	Cyproteron Acetate 2mg + Ethinylestradiol IP 0.035mg + Folic Acid IP 5mg Film Coated Tablets
10	Synokem Pharmaceuticals	Cyproteron acetate 2mg + Ethinylestradiol 0.035mg Film coated tablet
11	1. Mepromax 2. Creative Health Care 3. Helios Pharmaceuticals 4. Universal Twin Labs 5. Curetech Skincare 6. Mepromax	1. Miconazole Nitrate 2.0%w/w + Fluocinolone Acetonide 0.01%w/w Cream 2. Miconazole Nitrate IP 2%w/w + Fluocinolone Acetonide IP 0.01%w/w Cream 3. Miconazole Nitrate IP 2.00%w/w + Fluocinolone Acetonide IP 0.01%w/w Ointment 4. Miconazole Nitrate IP 2%w/w + Fluocinolone Acetonide IP 0.01%w/w Cream 5. Miconazole nitrate 2.00%w/w + Fluocinolone acetonide 0.01%w/w cream 6. Miconazole Nitrate 2%w/w + Fluocinolone Acetonide 0.01%w/w + Methyl Paryben 0.15%w/w Cream
12	Mepromax	Fluocinolone Acetonide 0.025%w/w + Miconazole Nitrate 2.0%w/w + Neomycin Sulphate 0.5%w/w Cream
13	Syncom Healthcare	Fluocinolone Acetonide 0.01% + Neomycin sulphate 0.5% + Clotrimazole 1.0% topical cream

A meeting has been convened on **22.08.2014** to evaluate the above proposals.

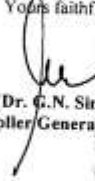
You are requested to kindly make it convenient to attend the said meeting on the said date.

TA/DA for attending the meeting as well as honorarium will be paid as per this Directorate's Office Memorandum No. 4-01/2013-DC (Misc13-PSC) dated 03.02.2014. **If travelled by Air, it should be by Indian Airlines only and the air tickets, if purchased through agent, should be purchased through M/s Balmaer Laurie & Co. who is the authorized Govt. agent for this purpose.**

You are requested kindly to make it convenient to attend the said meeting on **22.08.2014** at 11:00 a.m. to 6:00 p.m. in the Conference Room, 1st floor, FDA Bhawan, Kotla Road, Near National BalBhawan, New Delhi-110002.

You are requested to confirm your participation by e-mail at fdcddivision@gmail.com.

Yours faithfully,


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

Copy to:

1. M/s. Aurochem Laboratories (I) Pvt. Ltd. 333, Gundecha Ind. Complex, Akurli Rd, Kandivalli East Mumbai 400 101.
2. M/s. Rexcin Pharmaceuticals Pvt. Ltd. Address : D - 5, Okhla Industrial Area, Phase - I, New Delhi - 110020.
3. M/s. Universal Twin Labs, 29, THE MODEL CHS, SAHAKAR NIWAS, 20, TARDEO ROAD, Mumbai - 400034, Maharashtra.
4. M/s. Psychotropics India Limited, A-32, Sector -11, Opposite G. E. Motors, Faridabad, Haryana - 121007.
5. M/s. Yash Medicare Private Limited, 202, Panch Deep Complex, Behind Helmet House, Show Room, Mithakhali Six Road, Mithakhali Six Road, Ahmedabad, Gujarat 380009
6. M/s. East West Pharma, No. 10, 2nd Cross, Maravaneri, Salem - 636007, Tamil Nadu.
7. M/s. Gelnova Laboratories (I) Pvt. Ltd., C-125 TTC Industrial Area., Mahape (Pawane), Pawane Midc Road Number 7, Electronic Zone, Mahape, Navi Mumbai, Maharashtra 400705.
8. M/s. Sun Pharmaceuticals Industries Ltd., Tandajja, Vadodara-390020.
9. M/s. Akums Drugs & Pharmaceuticals Ltd., 19 to 21, Sector 6-A, IIE, Ranipur, Haridwar.
10. M/s. Zuventus Healthcare Limited, T-184, M.I.D.C., Bhosari, Pune-411026.
11. M/s. Glenmark Pharmaceuticals Ltd., B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai-400026.
12. M/s. Synokem Pharmaceuticals Pvt. Ltd, Plot No. 35/36, Sector 6A, IIE, SIDCUL, Ranipur, Haridwar-249403, Uttarakhand.
13. M/s. Mepromax Lifesciences Pvt Ltd., Sector I, Plot Number 16, Selaqui Industrial Area Pharma City Dehradun-248197, Uttarakhand.
14. M/s. Creative Health Care Pvt. Ltd., Plot NO. 25, Kundeshwari Village, kashipur, Udham Singh Nagar-244713 (Uttarakhand).
15. M/s. Helios Pharmaceuticals, (Div. of P.K.T.P. Pvt. Ltd.), 659/1, Gulbai Tekra, 2nd Lane Panchwati, Ahmedabad-380006.
16. M/s. Curetech Skincare, Plot No.34 Phase-IV, Bhatoli Kalan, Baddi, Himachal Pradesh 173205.
17. M/s. Syncom Healthcare Ltd., 221 Vyapar Bhawan, P.D. Mello Road , Mumbai-400 009 Maharashtra.

Note for Firms:

- You are requested to depute your technical team for presentation. As application for same FDC have been received from multiple applicants, you are requested to be present at CDSCO on **22.08.2014** at 11:00 a.m. to 6:00 p.m. in the Conference Room, 1st floor, FDA Bhawan, Kotla Road, Near National Bal Bhawan, New Delhi - 110 002 to make presentation as considered necessary by the committee.
- Also requested to submit the copy of the presentation of the respective proposals before 3 days of the meeting date.

- Also requested to bring Drug Samples in original pack as well as package insert while coming for presentation.
- Any other manufacturer who have applied above FDC's may also present their case before the committee.

Yours faithfully,



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