1. RECOMMENDATIONS OF THE NDAC (Pulmonary) HELD ON 03.12.2011:-

The NDAC (Pulmonary) deliberated the proposals on 03.12.2011 and recommended the following:-

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
Global Clinical Trials			
1	**BIBF 1120-150mg/100mg Cap**		Approved
2	**BIBF1120**		Approved
3	**Fluticasone Propionate**		In principle approved, subject to condition that the firm should submit satisfactory data to the office of DCG (I) in respect of following point before approval is considered. • How many sites were approached for selecting the sites proposed? • Sites should have paediatrics department to manage safety in case of emergency. At least co-investigator should be experienced with treating chest disease in paediatrics. • Details of ethics committee.
4	**QAW039**		Approved
5	**PH-797804**		Approved
6	**Fluticasone Propionate**		Rejected as the study is not ethical due to followings: • Placebo use in moderate asthma is medically unethical and dangerous which can lead to MLC. Use of placebo in patient with moderate asthma is not ethical as corticosteroid therapy is required to be given for such patients. • Dose findings study cannot be mixed with adult and adolescent.

New Drugs (FDC)			
1.	**Olopatadine Hydrochloride 665mcg + Fluticasone Furoate 13.75mg nasal spray**		The expert raised concern over the rationality of combining fluticasone furoate with olopatadine HCl as Fluticasone alone can address the most of the symptom in SAR. Further there is no data in support of selecting the dose in the proposed FDC. This FDC is not approved in any country. Therefore the experts did not recommend for the proposed Clinical Trial.
2.	**Paracetamol 325mg +Phenylephrine Hydrochloride 5mg+Chlorpheniramine 2mg Tablets**		The firm telephonically confirmed that they are going to withdraw the proposal, hence rejected.
3.	**Ambroxol 75mg + Levocetirizine 5mg + Montelukast 10mg tablets**		The firm has proposed this FDC for allergic rhinitis (AR). Use of Ambroxol is not justified for AR. Further, there is no supporting data on use of three drugs in combination. This FDC is not approved in any country. Hence, the proposal was not recommended.

2. RECOMMENDATIONS OF THE NDAC (Pulmonary) HELD ON 28.01.2012:-

The NDAC (Pulmonary) deliberated the proposals on 28.01.2012 and recommended the following:-

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
New Drugs			
1	**Roflumilast**		Committee opined that the drug seems to be safe and effective in COPD and it might be an addition to available drugs for the indication. However Phase III, 3-arm open comparative clinical trial of Roflumilast + Salmeterol vs Roflumilast + Tiotropium vs Roflumilast in at least 300 patients (100 in each arm) with 24 weeks duration of treatment in at least 4 centres geographically distributed in the country should be conducted. The efficacy assessment should include the assessment of FEV1 and reduction in exacerbation of COPD. Committee also advised that 50% of the clinical trial sites should be in multispeciality hospitals. Ethics Committee should be from the same area where the site is located. Accordingly revised clinical trial protocol, names of sites etc should be submitted for approval of DCG(I). Committee also recommended that all the applicants for this drug should be asked to conduct the clinical trial as above. Single dose bioequivalence study should also be conducted comparing with innovator's product as per the protocol submitted by M/s Sun Pharma. Results of local clinical trial and bioequivalence study when completed as above should be placed before the committee for taking decision on approval of the drug in the country.
2	**Bovine Lung Surfactant**		The product seems to be safe and effective. However Committee recommended that phase III clinical trial with the drug should be conducted. Accordingly protocol etc. should be submitted for consideration of the committee. The protocol etc would be deliberated in the next meeting. Two neonatologists should also be invited to participate in the deliberation in the next meeting.
3	**Bamifylline Hydrochloride**		Committee opined that the drug seems to be safe and effective as an additional bronchodilator. The committee recommended for granting permission to conduct the proposed clinical trial as per the

			protocol submitted subject to the following conditions:- i) Spirometry assessment should be included in the protocol at the time of enrolment of subjects as well as during the study. ii) Study should be completed in 200 patients, 100 each in asthma and COPD patients. It was also advised that i) sites should be geographically distributed in the country. ii) 50% of the clinical trial sites should be in multispeciality hospitals. iii) Ethics Committee should be from the same area where the site is located. Bioequivalence study as proposed may also be approved. Results of local clinical trial and bioequivalence study when completed as above should be placed before the committee for taking decision on approval of the drug in the country.
4	**Fenspiride**		Committee noted that the firm has proposed the drug for different indications viz. diseases of upper and lower respiratory tract: -nasopharyngitis and laryngitis; tracheobronchitis; bronchitis (with chronic respiratory failure or not); bronchial asthma (combined therapy); respiratory effects (cough hoarseness, sore throat) for measles, whooping cough, flu; respiratory infections, accompanied by a cough, when shown a standard antibiotic therapy; otitis media and sinusitis different etiologies. Committee recommended that trial should be conducted on at least 100 patients in each of indications viz. rhinosinusitis and as add on therapy in asthma. Accordingly protocol etc should be submitted for approval of DCGI. It was also advised that i) sites should be geographically distributed in the country. ii) 50% of the clinical trial sites should be in multispeciality hospitals. iii) Ethics Committee should be from the same area where the site is located.
5	**Paracetamol**		Committee noted that the proposed FDC of the

	325mg + Tripolidine 2.5mg + Phenylephrine 10mg + Caffeine 30mg sachets		four drugs is not available in any country. There is no data in support of the proposed FDC. Also for common cold, all the four drugs may not be required. Therefore committee opined that the proposed FDC is irrational, hence not recommended for approval.
Global Clinical Trials			
6	**Tiotropium + Olodaterol**		Recommended for approval with following advice:- i) Patients aged ≥ 40 yrs and ≤ 80 yrs should be enrolled in the study. ii) Sites should be geographically distributed in the country. iii) 50% of the clinical trial sites should be in multispeciality hospitals. iv) Ethics Committee should be from the same area where the site is located.
7	**Tiotropium + Olodaterol**		Recommended for approval with following advice:- i) Patients aged ≥ 40 yrs and ≤ 80 yrs should be enrolled in the study. ii) Sites should be geographically distributed in the country. iii) 50% of the clinical trial sites should be in multispeciality hospitals. iv) Ethics Committee should be from the same area where the site is located.
8	**Fluticasone Furoate**		During presentation, the firm presented before the committee that the proposed study is already approved in several countries including USA. The committee recommended for approval subject to submission of Regulatory approvals from other participating countries. The study may be approved with the following advice. i) Sites should be geographically distributed in the country. ii) 50% of the clinical trial sites should be in multispeciality hospitals. iii) Ethics Committee should be from the same area where the site is located.
9	**Bosentan**		Recommended for approval with the following advice.

			i) Sites should be geographically distributed in the country. ii) 50% of the clinical trial sites should be in multispeciality hospitals. iii) Ethics Committee should be from the same area where the site is located.
10	Reslizumab		The firm confirmed through email that the Sponsor is going to withdraw the proposal, hence proposal may be treated as withdrawn.

3. RECOMMENDATIONS OF THE NDAC (PULMONARY) DELIBERATED THE PROPOSALS ON 07-06-2012:-

The NDAC (Pulmonary) deliberated the proposals on 07-06-2012 and recommended the following:

Agenda No.	Drug Name		Recommendations
	Fixed Dose Combination		
1.	**Acebrophylline 100mg+Olopatadine5mg Tablet**		The proposed FDC is not approved in any country. The combined disease i.e asthma and allergic rhinitis is not prevalent in all cases together. Acebrophylline is given for a long term whereas for rhinitis there is no need for long term treatment with Olopatadine. As there is no rationale for the proposed FDC, committee did not recommend for giving marketing permission of the FDC.
2.	**Montelukast 5mg/4mg+Fexofenadine 60mg/30mg tablets**		The applicant did not appear for technical presentation. The proposed FDC is not approved for children anywhere in the world. Due to lack of safety and efficacy data of proposed FDC in children, committee did not recommend for giving marketing permission of the FDC.
3.	**MDI-Formoterol Fumarate 12mcg+Fluticasone Propionate 500mcg MDI**		Committee did not consider the proposed higher strength of the FDC as rationale as it may increase the toxicity and also has a chance of misuse. Hence committee did not recommend for giving marketing permission to the proposed higher strength of the FDC.
	DPI-Formoterol Fumarate 12mcg+Fluticasone		Committee did not consider the proposed higher strength of the FDC as rationale as it may increase the toxicity and also has a chance of misuse.

4.	**Propionate 500mcg DPI**		Hence committee did not recommend for giving marketing permission to the proposed higher strength of the FDC
5.	**Ebastine 10mg+Phenylephrine 10mg Tablet**		Such FDC may be required for small percentage of patients, that too for very short period. However, this FDC shall have chance of being misused. This FDC is not approved anywhere in the world. Thus the FDC is not essential. Hence committee did not recommend for approval of the proposal.
6.	**Ebastine 10mg+Montelukast 10mg Tablet**		The experts opined that the combination is rationale. However, clinical study is required to assess the safety and efficacy of the product. The clinical trial proposal includes study in asthma patients also, which needs to be totally excluded. The power of the study is 80% only which needs to be at least 90%. The subject in each arm should be at least 250. The committee recommended the approval of the proposal with following conditions:- 1.The clinical trial sites should be distributed geographically across the country. 2.50% of the sites should be at multispecialty hospitals including medical colleges. Revised protocol incorporating the above changes should be submitted to DCG (I) for his consideration and approval along with the Chemical and Pharmaceutical data. The clinical study report should be placed before the committee for further consideration.
7.	**Budesonide**		Committee did not consider the proposed higher strength of the FDC as rationale as it may increase the toxicity and also

	400mcg+Formoterol Fumarate 12mcg capsule for dry powder inhalation (DPI/MDI)		has a chance of misuse. Hence, committee did not recommend for giving marketing permission to the proposed higher strength of the FDC.
8.	**Chlorpheniramine Maleate 2mg/4mg+Levocloperastinel Fendizoate 20mg Oral Suspension**		Committee did not consider the proposed FDC as rationale as single drug, Levocloperastine Fendizoate would take care of both peripheral and central receptors for cough. The proposed FDC is not approved anywhere in the world. Hence, committee did not recommend for giving approval of the proposal.
9.	**Beclomethasone 50mcg+Salbutamol 100mcg Pressurized Inhalation**		The proposal is a therapeutic equivalence study for export purpose as per ANVISA requirement. The study is not for considering marketing approval in the country. The study is for short duration (10 days treatment). The committee recommended the approval of the proposal with following conditions: 1.The clinical trial sites should be distributed geographically across the country. 2.50% of the sites should be at multispecialty hospitals including medical colleges.
10.	**Acebrophylline 200mg (SR)+Montelukast 10mg tablets**		The proposed FDC is not approved in any country. This combination may be useful in very limited no. of patients and there are chances of misuses of this FDC. As there is no rationale for the proposed FDC, committee did not recommend for giving marketing permission of the FDC.
			Once a daily combination of Budesonide, Formoterol Fumarate and Tiotropium Bromide is not rational as both

11.	**Budesonide 200mcg+Formoterol Fumarate 6mcg+Tiotropium Bromide 9mcg MDI**		Budesonide and Formoterol is recommended to be given twice daily whereas tiotropium bromide is given once daily. The proposed FDC is not approved anywhere in the world. Also there is no data on once a day dosing of the combination. Therefore, the committee did not recommend the product.
	New Drugs		
12.	**Tulobuterol Transdermal Patch**		Tulobuterol is a long acting beta agonist. As per the current guidelines for asthma patients LABA+Steriod are recommended. Hence, any addition of patch of Tulobuterol is not justified. Moreover, tulobuterol alone cannot be used in asthma. In view of above, the committee did not recommend the product for the proposed indications.
13	**Garenoxacin Mesylate 200mg Tablet**		Committed noted that, on 25th July, 2007 Schering-Plough Europe officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for marketing authorization for Garenoxacin Mesylate 400mg and 600mg film-coated tablets and 2mg/ml solution for infusion, for the treatment of bacterial infections. The main concern of CHMP was that there was not enough evidence to demonstrate the medicine's effectiveness in treating some of the infections that it was expected to be used for. Furthermore, the CHMP has concerns over the side effects of Garenoxacin Mesylate, particularly a risk of low blood pressure. It was also unclear whether the medicine has an effect on the control of glucose (sugar) levels in the body. Therefore, at

			the time of withdrawal, the CHMP's view was that a benefit of Garenoxacin Mesylate had not been sufficiently demonstrated and any benefits did not outweigh the identified risks. The drug is only approved in Japan and the committee also observed that the data generated in India is not adequate. In view of above, the committee did not recommend to grant the permission of the product.
14.	**Cefpodoxime Proxetil SR 400mg Tablet**		Committee recommended for giving permission to conduct the study subject to the following conditions:- 1.The subjects for each study should be statistically significant in number. 2.50% of the study sites should be multispecially hospitals including medical colleges and the sites should be geographically distributed across the country. 3.Report of the BE study should be submitted to DCG (I) before initiation of the clinical trials.
Global Clinical Trial			
15.	**Choline Chloride**		Data submitted by the applicant is not as per Schedule Y of D & C Rules. The firm is required to submit adequate preclinical and clinical data as per Schedule Y for further evaluation by the NDAC.
			Committee recommended for giving permission to conduct the study with

16	**NVA237 (Protocol No.- CNVA237A2309)**		following conditions: 1.The clinical trial sites should be distributed geographically across the country. 2.50% of the sites should be at multispecialty hospitals including medical colleges.
17	**NVA237 (Protocol No.- CNVA237A2314)**		Committee recommended for giving permission to conduct the study subject to condition that investigation should be done for each subject for diagnosis of α-1 antitrypsin deficiency. Dr. J.C. Suri did not take part in the decision making process of the proposal during the meeting.
18.	**Symbicort pMDI (Budesonide & Formoterol Aerosol for oral Inhalation)**		As per the proposal, there is a request for exemption for reporting of SAEs within the stipulated timelines as per Schedule 'Y'. However, the same is not acceptable. Committee recommended for giving permission to conduct the study subject to condition that all unexpected SAEs should be reported to DCG (I) as per the timelines prescribed in Schedule Y of D & C Rules.
	Biological Division		
19	**(Palivizumab 100mg/ml)**		Committee recommended for giving permission to conduct the proposed BE study subject to submission of CMC data in CTD module. However, for considering the proposal for marketing approval, comparative clinical trial should be conducted on statistically significant number of subjects in sites geographically distributed across the country.

4. RECOMMENDATIONS OF THE NDAC (PULMONARY) DELIBERATED THE PROPOSALS ON 02.11.2012:-

The NDAC (Pulmonary) deliberated the proposals on 02.11.2012 and recommended the following:-

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
1	**Seratrodast**		The firm presented data on safety and efficacy of the drug including results of local clinical trial and bioequivalence study conducted in Indian population. The results shows that the drug seratrodast is not inferior to montelukast as add on therapy in bronchial asthma. Committee recommended for giving permission to manufacture and market seratrodast 40mg/80mg tablet as add on therapy in bronchial asthma.
2	**Mometasone Furoate 100 mcg, 200 mcg & 400 mcg metered dose Inhaler and Capsules for Dry powder inhalation**		The application of the firm was considered for only dry powder inhaler (DPI). Committee recommended that the firm should revise the clinical trial protocol to conduct a three arm study of mometasone furoate 400mg od vs mometasone furoate 200mg bd vs budesonide 200mg bd in patients with bronchial asthma. The clinical trial sites should be multispecialty hospitals including Govt Medical colleges/hospitals. The firm should submit revised protocol etc as above to DCG(I) for his approval.
3	**Lidocaine Lozenges 200/300mg**		Committee recommended for giving permission to conduct the proposed phase III clinical trial subject to condition that the study should be multicentric study in at least 4 centres geographically distributed in the country which should be multispecialty hospitals including Government medical colleges/hospitals. The number of subjects in the study should be at least 200 in 2:1:1 ratio for lidocaine lozenge, spray and gargle respectively.

4	**Azelastine + Mometasone**		It may be mentioned that FDC of Corticosteroid with any other drug for internal use except for preparations meant for meter dose inhalers and dry powder inhalers is banned under section 26A of the Drug and Cosmetics Act, 1940 vide GSR 738 (E) dated: 09.10.2009. In this FDC the content of Azelastine is 140 mcg. However, each spray will deliver 137mcg. The committee opined that the FDC of mometasone furoate + azelastine hydrochloride nasal spray is a topical formulation and not for internal use. Hence, this FDC does not fall under the purview of the said notification and hence is not a banned drug. M/s. Glenmark & M/s. Cipla presented their proposal of conducting clinical trial with the FDC for export purpose. The committee recommended for giving permission to conduct the proposed clinical trial in adult patients for export purpose to both Glenmark and Cipla. However, in case of Cipla, the study site should be multispeciality hospitals including government medical colleges / hospitals and details of sites etc. should be submitted to DCG(I) before formal approval of the study by DCG(I).
5	**Budesonide + Formoterol Fumarate**		Committee recommended for giving permission for the clinical trial for export purpose.
6	**AM3301**		Committee observed that there are effective oral and topical treatment options available for the treatment of allergic rhinitis. From the proposal it was not clear that the proposed oral therapy with AM3301 will have superiority over existing treatment options. Therefore the committee recommended that

			the firm should submit safety results from the ongoing ulcerative colitis study in Indian subjects as well as safety results from the proposed clinical study ongoing in Malaysia.
7	**Mometasone Furoate / Formoterol Furoate**		Committee recommended for giving permission for the study subject to condition that sites involved in the study should be multispeciality hospitals including government medical colleges / institutions. The details of such sites etc. should be submitted to DCG(I) before formal approval of the study.
8	**Mometasone Furoate**		Committee recommended for giving permission to conduct the study subject to condition that upper age limit of subjects to be included in the study should be 65 years.
9	**QVAN149**		Committee recommended for giving permission to conduct the study subject to the following conditions:- **i)** The patients with FEV1 between 50% and 80% should be included in the study. **ii)** Upper age limit of subjects to be included in the study should be 80 years.
10	**Mometasone Furoate**		Mometasone Furoate MDI in asthma is not yet approved in India for adults. Further in the proposed study, there is an arm the patients of which will be given only placebo which has ethical issue. Therefore committee did not recommend for giving permission to conduct the study.
11	**Fluticasone + Salmeterol**		US FDA conducted a meta-analysis using data provided by Astra Zeneca, GlaxoSmithKline and Novartis which suggested a potential risk of serious asthma outcomes on use of LABA with ICS. There remains a public health debate whether the use of a LABA with an ICS increases the risk of serious asthma outcomes. In order to further assess the safety of salmeterol in combination with Fluticasone, this study is

			proposed to be conducted globally in 35 countries in more than 11000 patients. The results of the study would be beneficial for Indian patients also. Therefore committee recommended for giving permission to conduct the study. However the study should be conducted in multispecialty hospitals including Government medical colleges/hospitals. Details of such sites etc. should be submitted to DCG(I) for his approval.
12	**BIBF1120**		Committee recommended for giving permission to conduct the study.
13	**CINRYZE (C1 Esterase Inhibitor Human)**		Hereditary angioedema is a rare and life threatening disease for which currently there is no definite treatment options. Therefore committee agreed for waiver of local clinical trial and recommended for giving permission to import and market the drug for the treatment and routine prevention of angioedema attacks. However the firm should collect the post marketing safety data of each treatment case and submit the data to the committee within two years for examination.
14	**Alair Bronchial Thermoplasty Catheter**		Committee recommended that the firm has to carry out clinical trial in India before its approval for marketing in India as similar device was not approved in India.
15	**Tulobuterol Transdermal Patch**		The firm has changed their claim for this drug from asthma to COPD. However committee observed that safety and efficacy data of the drug in COPD is inadequate. Hence committee recommended that a well designed controlled clinical trial in statistically significant number of patients with COPD should be conducted. Accordingly the firm should submit protocol etc. for examination by the committee.
16	**Magnesium sulphate**		Intravenous Magnesium sulphate is used in

			respiratory disorders. Bronchiolitis is a disease predominantly in young children. The Committee recommended for giving permission to conduct the study. However before formal approval by DCGI, the applicant should submit approval of Ethics Committee of the institute and Informed Consent Documents. The Ethics Committee of the institute should closely monitor the study.

5. RECOMMENDATIONS OF THE NDAC (PULMONARY) DELIBERATED THE PROPOSALS ON 26.04.2013:-

The NDAC (Pulmonary) deliberated the proposals on 26.04.2013 and recommended the following:-

AGENDA NO.	NAME OF DRUG		RECOMMENDATIONS
1 to 6	**Special Agenda** **1. Bosentan (as monohydrate) Tablets 62.5/ 125mg** **2. Ambrisentan Tablets 5/10mg** **3. Pirfenidone Tablets 200mg** **4. FDC of nimesulide with levocetirizine** **5. FDC of gemifloxacin with ambroxol** **6. Doxophylline**		The Committee was apprised that the Parliamentary Standing Committee (PSC) for the Ministry of Health & Family Welfare had presented its 59th report to the Parliament on 08.05.2012 on the functioning of the CDSCO. The report has made various recommendations and observation on various aspects such as approval of New Drugs, Pharmacovigilance, approval of clinical trials etc. The Ministry of Health & Family Welfare has submitted final action taken report on the observation/recommendations contained in the 59th report of the Hon'ble Parliamentary Standing Committee. As per the action taken report, it has been decided by the Ministry that 73 drugs including Fixed Dose Combinations, on approval of which the Hon'ble PSC has made various observations, would be referred to the NDACs for examination and review related to continued marketing of these drugs and updating of their product monographs in light of recent knowledge and regulatory changes overseas. Out of these 73 drugs, 6 drugs are in the category of Pulmonarywhich is given below:- 1. Bosentan (as monohydrate) Tablets 62.5/ 125mg 2. Ambrisentan Tablets 5/10mg 3. Pirfenidone Tablets 200mg 4. FDC of nimesulide with levocetirizine

			5. FDC of gemifloxacin with ambroxol 6. Doxophylline The NDAC (Pulmonary) discussed the issue and noted that Ministry of Health & Family Welfare has already constituted a Committee to formulate policy guidelines and SOPs for a) approval of new drugs, clinical trials, and banning of drugs under the Chairmanship of Dr. Ranjit Roy Chaudhury and b) for approval of the Fixed Dose Combinations under the Chairmanship Dr. C.K. Kokate. Therefore, the Committee opined that these drugs related to continued marketing and updating of the product monograph in the light of recent knowledge and regulatory changes overseas could be examined as per policies, guidelines and SOPs being prepared by the Dr. Ranjit Roy Chaudhury Committee and Dr. C.K. Kokate Committee. However, in the meantime the data/information on safety, efficacy of this drug including published data, PMS/PSUR, PSUR data especially on Indian patient required to be prepared in the Form of Dossier. Such data should be prepared from three different sources viz. i) by CDSCO ii) by PharmacovigilanceProgramme of India (PvPI) and iii) the firm concerned. The Dossier shall be circulated to all the experts of the NDAC (Pulmonary) for their further review. If needed manufacturer may be requested to make their Presentation before the NDAC on safety and efficacy of the drug. The NDAC further recommended the following :- CDSCO may collect the following information on the drug

			i) The date of approval of the drugs. ii) The date of manufacturing and marketing of the drugs by the manufacturer. iii) The mandatory PSUR reports submitted by these companies. iv) Pharmacovigilance data if any from PVPI on the drugs. v) Marketing status of the drugs. vi) Global Marketing status of the drugs. vii) Clause, condition and opinion under which permission was granted for the drugs. As soon as the above information is available, a meeting may be called. In the meeting, the recommendations of the other 2 committees may be placed which would be discussed.
7	**CefcapenePivoxil**		The firm was not able to demonstrate the superiority/noninferiority of cefcapene over the available drugs of its class. This drug is available only in Japan since 1997 and comparative safety data was not provided before the committee. In the proposed clinical trial, comparative drug i.e Amoxycillin + Clavulonic acid was not appropriate; it should be compared with the available 3rd generation cephalosporin. Therefore, the committee recommend for change in clinical trial protocol and submit the proposal to the DCG(I) for evaluation.
8	**Bilastin 20 mg Tablets**		Committee recommended for giving permission to conduct the proposed study at sites having Institutional Ethics Committee and the sites should be geographically distributed across the country. Before granting approval, the approval status of the drug in EU should also be checked.

9	**Glycopyrronium Bromide Dry inhalation powder Cap 50 Mcg**		The firm presented Phase III clinical trial data conducted on Indian population and based on data presented, committee recommended for approval of Glycopyrronium Bromide Dry inhalation powder Cap 50 Mcg.
10	**MometasoneFuroate Nasal Spray 50mcg/dose**		Committee recommended for the approval of the MometasoneFuroate Nasal spray 50mcg/dose.
11	**MethylPredisolone Tablets 4/8/16mg**		Committee recommended for approval of the proposed additional indication.
12	**Guaifenesin 600mg ER tablet**		Committee recommended for approval of PhaseIV Clinical Trial of Guaifenesin 600mg ER tablet with a condition that the clinical trial site should be geographical distributed site and in patients 18 years above and medical college/Govt. Hospital.
13	**Hydrobromide + Phenylephrine Hydrochloride + Triprolidone**		Committee opined that the firm could not present any scientific evidence for the rationality of combining these 3 drugs. Further firm could not provide any evidence with respect to equivalency between oral spray dose proposed viz a viz oral dose of the FDC during the presentation. Hence, the committee did not recommend the proposed protocol for FDC.
14	**Fluticaosne Propionate/ Salmeterol**		Committee recommended for the approval of the proposed protocol. However, the study sites should be multi-specialty with emergency facilities, out of which 50% should be government hospitals.
15	**QVA149**		Committee recommended for approval of clinical trial with condition that exclusion criteria should mention cardiac patients “should not be included in the proposed clinical trial”.

16	**QVA149**		Committee recommended for giving permission for the study. However, the study sites should be multi-specialty with emergency facilities, out of which 50% should be government hospitals.
17	**QVA149**		Firm has withdrawn the application.
18	**Garenoxacin Mesylate 200 mg Tablets**		Committee opined that the firm presented data regarding the concerns raised by NDAC on 07.06.2012 were addressed by the company. The committee after detailed deliberation recommends for the market approval of the proposed drug GarenoxacinMesylate 200 mg tablets for the treatment of bacterial respiratory tract.
19	**Tulobuterol Transdermal Patch**		Committee after detailed deliberation recommended that a well designed controlled clinical trial in statistically significant number of patients with COPD should be conducted. Accordingly, protocol etc. should be submitted for examination.
20	**Procaterol**		Committeerejected the proposed protocol by the firm.

6. RECOMMENDATIONS OF THE NDAC (PULMONARY) DELIBERATED THE PROPOSALS ON 06.08.2013:-

The NDAC (Pulmonary) deliberated the proposals on 06.08.2013 and recommended the following:-

Agenda no.	Drug Name		Recommendations
1.	Neltenexine monohydrate 37.4 mg tablet		The proposed drug Neltenexine monohydrate 37.4 mg tablet is marketed only in one country i.e Italy and published clinical data submitted by the firm is on < 400 patients. The committee opined that the mucolytic has no established role in the treatment of COPD. Hence committee did not found any rational for consideration of proposal submitted by the firm.
2.	Guaifenesin Oral Solution 100 mg/5ml		The committee opined that Guaifenesin Oral Solution 133 mg/5ml is already approved for use in adult population. The firm has asked that the additional strength 100mg/5ml oral solution. In this dose the drug will be misused in children. The Guaifenesin is not approved for use in children below 12 yr internationally. Therefore by permitting this 100mg/5ml additional dose will not add any benefit. There for committee does not recommend the approval of proposed additional strength.
3.	Salbutamol pressurised inhalation (pMDI)-100 mcg per actuation		Committee recommended for granting approval to conduct clinical trial as test product being approved drug with the condition that trial should be conducted in multi specialty hospital/government hospital distributed geographically all across India as per protocol submitted.
4.	Dextromethorphan Hydrobromide Syrup 7.5mg/5ml		The firm has proposed the lower strength of Dextromethorphan Hydrobromide Syrup 7.5mg/5ml for use in Pediatric patients. This drug has proven safety data for use in children. The committee does not recommend the approval of new proposed strength for use in pediatrics population.
5.	Umeclidium		Proposal withdrawn by firm.

7. RECOMMENDATIONS OF THE NDAC (PULMONARY) DELIBERATED THE PROPOSALS ON 09.11.2013:-

The NDAC (Pulmonary) deliberated the proposals on 09.11.2013 and recommended the following:-

Agenda no.	Drug Name		Recommendations
1.	Choline Chloride		Choline is a dietary component, occurs both as free choline and as phosphatidylcholine (PC), such as lecithin, in egg yolk, vegetables and animal fat. It is important for the structural integrity of cell membranes, methyl group metabolism, cholinergic neurotransmission, trans-membrane signaling, lipid and cholesterol transport and general metabolism. Choline reported to have a wide use as a food additive since the early/1930s. The applicant has proposed a clinical trial of Choline chloride formulation through inhalation/intranasal route. However, no such clinical trial through inhalation/intranasal route has been conducted /presented. The applicant presented the published clinical trial data of choline trough oral route, which shows the drug is safe in these trials. In view of above, the committee recommended that based on the data the proposal for intranasal route/inhalation route cannot be approved. The applicant should initially conduct clinical trial of Choline Chloride formulation in asthma patients through oral route. Accordingly protocol, ICF, undertaking by the investigator etc., should be submitted for the examination by the committee. Dr. Rajendra Prasad did not take part in the Decision making process.
2.	Tulobuterol Transdermal Patch		Firm did not turn up for presentation & requested for deferment of proposal in next NDAC meeting.
3.	Fluticasone		Firm did not turn up for presentation & requested for deferment of proposal in next NDAC meeting.

4.	QVA149		Firm has withdrawn proposal
5.	Fluticasone		Firm did not turn up for presentation & requested for deferment of proposal in next NDAC meeting

8. RECOMMENDATIONS OF THE NDAC (PULMONARY) DELIBERATED THE PROPOSALS ON 29.01.2014:-

The NDAC (Pulmonary) deliberated the proposals on 29.01.2014 and recommended the following:-

Agenda no.	Drug Name		Recommendations
1.	**Fenspiride extended tablet 80mg**		The Committee was informed that in its earlier meeting held on 28-01-2012, the committee had recommended that clinical trial is required to be conducted on at least 100 patients in patients with disease of the upper and lower respiratory tract nasopharyngitis and laryngitis; tracheobronchitis; bronchitis (with chronic respiratory failure or not); bronchial asthma (combined therapy); respiratory effects (cough hoarseness, sore throat) for measles, whooping cough, flu; respiratory infections, accompanied by a cough. Firm presented the data in detail in respect of two protocols: 1. Acute rhinosinusitis 2. Treatment of moderate persistent asthma as an addon therapy. After deliberation the committee recommended for the conduct of these two clinical trial i.e. for acute rhinosinusitus and asthma subject to the condition that more study centre is required to be added other than in the West Zone of the country in the clinical study in rhinosinustitis.
2.	**Roflumilast**		The firm presented the safety and efficacy data of drug including results of two clinical trial conducted in India as a part of global clinical trial wherein 456 patients were enrolled in these studies. The results of these

			two clinical trials showed that the safety and efficacy profile of the drug in Indian patients is comparable to the global data. After deliberation the committee recommended for the approval of drug for the proposed indication. Keeping in mind to some concern on tolerability of the drug, the Committee also recommended that PMS (Phase IV clinical trial) is required to be conducted in at least 1000 patients after Clinical trial protocol etc., duly approved by DCGI.
3.	**Tulobuterol Transdermal Patch**		The firm initially applied for the import and marketing of Tulobuterol Transdermal Patch proposed to be indicated for the remission of various symptoms such as dyspnea due to obstructive airway disorder in the following diseases: bronchial asthma, acute bronchitis, chronic bronchitis and pulmonary emphysema. The Committee in its earlier meeting held on 26.04.2013 had recommended that a well-designed controlled clinical trial in statistically significant number of patients with COPD should be conducted. Accordingly, protocol etc. should be submitted for examination. Now the firm made detailed deliberation on the clinical trial data generated on patients with asthma and COPD in the country. The committee after deliberation recommended for approval of the drug in patients with Asthma and COPD without co-morbidity subject to condition that PMS (Phase IV clinical trial) is required to be conducted in at least 1000 patients after Clinical trial protocol etc. duly approved by DCGI.

4.	**Bosentan**		Firm requested deferment of the proposal in next NDAC meeting
5.	**Montelukast Sodium Mouth Dissolving Films 4/5/10mg**		The proposed Montelukast Sodium Mouth Dissolving Film is not approved internationally. After due deliberation the committee recommended that a phase III clinical trial required to be carried out, accordingly clinical trial is required to be submitted for further review by the NDAC committee.
6.	**Indacaterol Maleate + Glycopyrronium Bromide 110mcg+50mcg**		The Firm presented the Fixed dose combination clinical trial data on Indian patients from earlier three clinical trial conducted globally. The committee after deliberation recommended for approval of the drug in patients with COPD subject to condition that PMS (Phase IV clinical trial) is required to be conducted in at least 1000 patients after Clinical trial protocol etc. duly approved by DCGI
7.	**QAW039-450mg capsule**		The firm has applied for the grant of permission to conduct a phase II clinical trial with QAW039 (450 mg OD) on FEV1 and ACQ in non-atopic, asthmatic patients with a baseline, pre-bronchodilator FEV1 of 40-80% predicted, inadequately controlled with low dose ICS (Fluticasone) therapy. The patients of atopic and non-atopic will be included in the trial. Salbutamol (SABA) will be the rescue medication. The trial drug is approved in EU and USA but not in India. The firm has presented their proposal before the NDAC Experts and the committee has recommended grant of permission to conduct the phase –III clinical trial subject condition that the upper age limit should not be beyond 65 years of age.