

Recommendations of the SEC (Pulmonary) made in its 54th meeting held on 29.09.2021 at CDSCO HQ New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	12-01/21-DC(PU-006) Beractant Intratracheal Suspension 25mg/ml (Sterile) in 4 ml and 8 ml single dose vial	M/s Abbott	The firm presented the proposal to update the package insert to include LISA technique for administration of the drug. The committee noted that the LISA technique is already in use in other countries. After detailed deliberation, the committee recommended for approval to incorporate the LISA technique in the prescribing information of the drug.
2.	ND/IMP/21/000018 Revefenacin inhalation solution 175 mcg /3ml	M/s Mylan	In light of SEC recommendation dated 07.04.2021, the firm presented Phase III CT protocol before the committee. After detailed deliberation, the committee recommended that the study should be comparative study of at least 12 weeks duration of treatment and assessment of quality of life should be a secondary end point. Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.
3.	12-01/12-DC (Pt-9) Cipla/Pirfenidone	M/s. Cipla	In light of SEC recommendation dated 26.02.2021 & 01.03.2021, the firm presented the Phase IV CT report before the committee. After detailed deliberation, the committee reiterated its earlier recommendations and opined for more data to be presented before the committee. The committee also suggested that the firm needs to conduct active surveillance study. Accordingly, protocol should be submitted for review by the committee.
FDC Division			
4.	FDC/MA/20/000119 FDC Bilastine10mg+Montelukast 4mg Oro dispersible tablet	M/s Akums Drugs & Pharmaceuticals Limited	The firm presented BE study results before the committee. After detailed deliberation, the committee recommended that firm may initiate phase III CT study for which permission has

			already been issued by CDSCO.
5.	FDC/CT/21/000072 Glycopyrronium 50mcg + Vilanterol 25mcg dry powder Inhalation vs Glycopyrronium 25mcg +Formoterol 12mcg dry powder inhaler	M/s JSS Medical Research Asia Pacific Private Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed phase-III clinical trial with the following conditions; 1. Patients should be reasonably equidistributed across the study sites. 2. Inhalation toxicity study should be conducted and report to be submitted to CDSCO before initiating the Phase-III Clinical trial
6.	FDC/CT/21/000071G Glycopyrronium 50mcg + Vilanterol 25mcg + Fluticasone dry powder Inhalation vs Glycopyrronium 12.5mcg + Formoterol 12mcg + Fluticasone 250mcg dry powder inhaler	M/s JSS Medical Research Asia Pacific Private Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee opined that; 1. Inhalation toxicity study should be conducted. 2. Inclusion and exclusion criteria are to be revised as per the patient population for which the proposed FDC is indicated. In view of above, the committee recommended that the firm should revise the Phase-III Clinical trial protocol for further review by the committee.
BA/BE Division			
7.	12-09/2021/BA- BE/MISC-17/DC Budesonide 80 µg and Formoterol Fumarate Dihydrate 4.5 µg Inhalation	M/s. Cipla Limited, Mumbai-400013	The firm presented BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per proposal presented with recommendation that, more government sites should be included and sites should be geographically distributed throughout the country.

