Recommendations of the SEC (Pulmonary) made in its 76th meeting held on 21.09.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/23/000029 SuplatastTosilate 100mg Capsule	M/s. Syngene International Limited	In light of earlier SEC recommendation dated 06.06.2023, the firm presented justification/clarification before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II study. The committee recommended that the firm should also evaluate safety in the proposed study and submit revised protocol to CDSCO.
SND Division			
2.	SND/MA/23/000046 12-SQ-HDM Sublingual Lyophilisate (Sensimune)	M/s. Dr. Reddy's Labs Pvt. Ltd.	The firm presented their proposal for Import & marketing of 12 SQ-HDM sublingual lyophilisate Tablet (Dermatophagoide spteronyssinus and Dermatophagoides farinea) along with justification for Phase III clinical trial waiver before the committee. After detailed deliberation, the committee recommended that the firm should submit clarification whether applied product is of synthetic origin or biological origin. Also, the firm should submit detailed dosage regimen, Duration of treatment and Indication for the proposed product to CDSCO for further review by the Committee.
FDC Division			
3.	FDC/MA/22/000239 Glycopyrrolate IP eq. to Glycopyrronium + Fluticasone Furoate + VilanterolTrifenatate eq. to Vilanterol 50mcg/50mcg+100mcg/200mcg+25mcg/25 mcg Powder for inhalation in capsule	M/s. Glenmark Pharmaceuticals Ltd.	In light of earlier recommendation of SEC dated 29.09.2022, the firm presented their proposal along with justification for safety of the 200 mcg dose of Fluticaosne Furoate in three drug combination in uncontrolled asthma along with Phase III CT Protocol before the committee. After detailed deliberation, the committee considered the safety of the 200 mcg dose of Fluticaosne Furoate in combination

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			and recommended that: 1. The study arm for Glycopyrronium 50 mcg + Fluticasone Furoate 200 mcg + Vilanterol 25 mcg should be separate in the Phase III CT Protocol. 2. The study arm for Glycopyrronium 50 mcg + Fluticasone Furoate100 mcg + Vilanterol 25 mcg should also be separate with proper justification in the Phase III CT Protocol. 3. More Govt. sites shall be included in the study with geographical distribution in Phase III CT Protocol. Accordingly, firm should submit revised Phase III CT Protocol to CDSCO for further review by the committee