Recommendations of the SEC (Pulmonary) made in its 62nd meeting held on 31.08.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/21/2021/8941 Indacaterol (as acetate) 150 mcg and Mometasone furoate 80/160/320 mcg Dry powder for inhalation (DPI)	M/s. Glenmark Pharma Ltd.	The firm presented their proposal for waiver of active post marketing surveillance. After detailed deliberation, the committee did not agree with the request of waiver and recommended that firm should conduct the active post marketing surveillance study as per the condition of the manufacturing permission.
FDC Division			
2.	FDC/MA/20/000029 Montelukast IP 4mg + Fexofenadine Hydrochloride IP 60mg Suspension	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 01.10.2020 & 07.06.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee opined that the firm should present a phase III CT protocol before the committee for further review and ENT specialist may also be invited.
3.	FDC/MA/21/000147 Indacaterol maleate eq. to Indacaterol 75mcg/ 150mcg+ Budesonide IP 200mcg/ 400mcg Dry powder for inhalation	M/s. Zydus Healthcare Ltd.	In light of earlier SEC recommendation dated 31.08.2021, the firm presented the Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of the proposed FDC.
4.	FDC/MA/21/000156 Vilanterol Trifenatate eq. to Vilantero 112.5mcg/12.5mcg + Fluticasone furoate 50mcg/100mcg metered dose inhalation	M/s. Zydus Healthcare Ltd.	In light of earlier SEC recommendation dated 31.08.2021, the firm presented the Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of the proposed FDC.
GCT Division			
5.	CT/168/21 Online Submission (18943) Fluticasone propionate inhalation aerosol USP 44 mcg	M/s. Glenmark	The applicant presented protocol amendment version 3.0 dated 10 June 2022, before the committee. After detailed deliberation, the committee recommended for grant permission to conduct study with amended protocol.