Recommendations of the SEC (Pulmonary) made in its 01/24 meeting held on 04.01.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/51/23 Online Submission (29648) Dated 20/11/2023 Astegolimab	M/s. PPD	The firm has presented protocol version 4.0 dated 20-June-2023, protocol No. GB44332. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment as presented by the firm & CTNOC condition No. (1) should remain same as approved earlier i.e. "Atleast 50% sites & subjects should be from the Govt. sites".
2.	CT/62/22 Online Submission (30103) Dated 12/12/23 SAR440340/REGN3500 - Itepekima	M/s. SANOFI	The firm has presented protocol 02, version 01 dated 27-Sep-2023, protocol No. EFC16750. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment as presented by the firm.
3.	CT/75/22 Online Submission (30109) Dated 12/12/23 SAR440340 / REGN3500 / Itepekimab	M/s. SANOFI	The firm has presented protocol 02, version 01 dated 26-Sep-2023, protocol No. EFC16819. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment as presented by the firm.
Biological Division			
4.	BIO/CT/21/000067 Omalizumab	M/s Veeda Clinical Research	The firm presented the clinical study report for the Phase-I PK-PD study titled as "A randomized, double blind, three-arm, parallel group, single dose comparative PK, PD, safety and immunogenicity study comparing ADL-018 with US licensed Xolair and EU-approved Xolair administered through subcutaneous route in healthy adult subjects" vide protocol No. OMA/2019/1692, version 5.0 dated 29.03.2022. After detailed deliberation the committee noted the results of the study.

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FDC Division			
5.	FDC/CT/23/000078 Budesonide IP 200 mcg + Formoterol Fumarate Dihydrate IP 6 mcg + Glycopyrronium IP 12.5 mcg aerosol for inhalation	M/s Cipla Limited	The firm did not turn up for presentation.
6.	FDC/CT/23/000080 Fluticasone Furoate 200mcg + Vilanterol Trifenatate eq. to Vilanterol 25mcg dry powder for inhalation in capsule	M/s Zydus Healthcare Limited	In light of the condition mentioned in permission in Form CT-23 dated 30.08.2023, the firm presented the Active PMS protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of the Active PMS study. The firm should submit the Active PMS study report to CDSCO for further review by the committee.
7.	FDC/CT/23/000085 Formoterol Fumarate Dihydrate IP 12 mcg + Budesonide IP 400 mcg + Glycopyrrolate IP eq. to Glycopyrronium 25 mcg powder for inhalation in capsule	M/s Penta Kraft	The firm did not turn up for presentation.
8.	FDC/CT/23/000091 Fluticasone Furoate 100 mcg + Glycopyrronium Bromide eq. to Glycopyrronium 50mcg + Vilanterol Trifenatate eq. to Vilanterol 25mcg Inhalation Powder in capsule	M/s. Lupin Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 26.09.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of the Phase IV clinical trial. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
9.	FDC/MA/22/000409 Ebastine IP 10 mg + Phenylephrine Hydrochloride IP	M/S. Micro Labs Ltd.	In light of earlier SEC recommendation dated 06.06.2023, the firm presented their proposal along with BE report before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	10mg tablets		The committee noted that CDSCO has already issued NOC for proposed FDC on 04.01.2022 under 18 months policy decision. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the FDC.