Recommendations of the SEC (Pulmonary) made in its 59th meeting held on 28.04.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/21/202/28941 Indacaterol (as acetate) 150 mcg and Mometasone furoate 80/160/320 mcg dry powder for inhalation (DPI)	M/s. Glenmark Pharma Ltd.	In light of the earlier SEC recommendation dated 07/12/2021, the firm presented their proposal along with the justification of BA study waiver and in vitro drug deposition study, published data and results of GCT of the F.D.C conducted by the other firm in which India was one of the participating countries before the committee. The committee noted that the drug is already approved by Europe, Australia, Canada and Japan. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC Indacaterol (as acetate) and Mometasone furoate Dry Powder for Inhalation (DPI) in Capsules for the proposed indication subject to the condition that the firm should conduct active post marketing surveillance for which protocol should be submitted to CDSCO within three months of approval of the drug.
FDC Division			
2.	FDC/MA/20/000119 Montelukast Sodium IP eq. to Montelukast + Bilastine (4mg + 10mg) Oro dispersible tablets	M/s Akums Drugs	In light of earlier SEC recommendation dated 29.06.2021, the firm presented their proposal along with the request for Phase III clinical trial waiver. The committee noted that the proposed FDC in same strength in suspension formulation has already been approved on 11.03.2022. The committee also noted that the firm has also conducted BE study for the applied FDC. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with condition that the firm should conduct Phase IV clinical study. Accordingly, Phase IV clinical trial protocol should be submitted to CDSCO within 3 months from the date of

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			approval.
3.	FDC/MA/22/000091 Bilastine 3.3mg + Dextromethorphan Hydrobromide 10mg + Phenylephrine Hydrochloride 5mg Syrup Hydrochloride 5mg Syrup	M/s Glenmark Pharmaceuticals	The firm presented the Phase III clinical trial protocol and requested for BE study waiver before the committee. During the presentation, the committee noted that Bilastine 6.6 mg t.i.d is not approved internationally. Clinical trial protocol for appropriate phase of the study should be revised accordingly and sedation should also be included in the clinical trial protocol as one of the endpoint. After detailed deliberation, the committee recommended that the firm should initially justify the dose of Bilastine in the proposed FDC for further review by the committee.
4.	FDC/CT/22/000001 Budesonide 400mcg + Formoterol Fumarate 12mcg + Glycopyrronium 25mcg	M/s. Zydus Healthcare	The firm presented their proposal along with Phase IV clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase IV clinical trial.
5.	FDC/MA/21/000240 Fluticasone Furoate +Vilanterol Trifenatate eq. to Vilanterol (100 mcg/200mcg+ 25mcg)Dry Powder for inhalation	M/s. Glenmark Pharmaceuticals Pvt. Ltd.	The firm presented their proposal before the committee along with first BA study results and second BA study protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed additional BA study. Results of the study should be presented before the committee for further consideration.
GCT Division			
6.	CT/141/21 MEDI 3506	M/s. AstraZeneca	The firm presented their justification before the committee for waiver of condition recommended by the SEC in earlier meeting. After detailed deliberation, the committee opined that the previous conditions recommended by SEC should be deleted and the protocol may be approved in its presented form.
7.	CT/165/21 Online Submission (29473)	M/s. Novartis	The firm presented their proposal before the committee for waiver of conditions

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	CSJ117		recommended by the SEC in earlier meeting. After detailed deliberation, the committee noted that the conditions were already mentioned in the protocol. Hence, the committee opined that the previous conditions recommended by SEC should be deleted and the protocol may be approved in its presented form.