Recommendations of the SEC (Dermatology & Allergy) made in its 64th meeting held on 15.12.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT/21/000052 Mupirocin 2.0%w/w in an ointment base containing Biopolymer: Poly-β -(1-4)-2 amino-2 deoxy-d-glucose (Chitosan)	M/s. Apex Laboratories	In light of earlier recommendation of SEC dated 13.10.2021 the firm presented the revised clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct of the clinical trial as per the protocol presented.
FDC Division			
2.	FDC/MA/20/000105 Halobetasol Propionate + Tazarotene (0.1mg + 0.45mg)topical lotion	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented their proposal along with BE study report. The committee noted that the test product was not bio equivalent in terms of rate and absorption with the reference product. After detailed deliberation, the committee recommended that the firm should conduct a comparative, randomized phase III clinical trial. Accordingly the firm should submit phase III clinical trial protocol for review by the committee.
GCT Division			
3.	CT/125/21 Online Submission (28349) SAR231893/Dupilumab	M/s. Sanofi	The proposal was deferred to the next meeting. The committee opined to invite one ENT Specialist in next SEC meeting for the deliberation of the proposal.
4.	CT/127/21 Online Submission (28408) Ligelizumab (QGE031)	M/s. Novartis	The firm presented the Phase III clinical trial protocol before the committee. **Assessment of risk versus benefit to the patient:** The safety profile of trial drug from various pre-clinical toxicity studies and clinical studies, may justify the conduct of the proposed trial. **Innovations Vs existing therapeutic option:** The purpose of the study is to investigate the efficacy and safety of Ligelizumab (QGE031) in the treatment of chronic inducible urticaria (CINDU) in

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			adolescents and adults inadequately controlled with H1-Anti Histamines. **Unmet medical need in the country:** The trial drug may be an alternative treatment option of chronic inducible urticaria (CINDU) in adolescents and adults inadequately controlled with H1-Anti Histamines. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the following conditions- 1. At least 50% sites from govt. sites should be included. 2. The firm should comply with the requirements for sampling of DNA biomarkers for Pharmacogenomic study and its shipping to other countries.