Recommendations of the SEC (Dermatology & Allergy) made in its 01st/24 meeting held on 11.01.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/27/23 Online Submission (30149) Dated 13/12/23 Amlitelimab 250mg/2ml solution (125 mg/ml)	M/s. SANOFI	The firm presented protocol amendment 01, version 01 dated 25 July 2023 protocol No. LTS17789. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
2.	CT/161/23 Online Submission (41040) Dated 19/12/2023 AKP02G2 cutaneous spray	M/s. Cliantha Research Limited	The firm presented phase III clinical study protocol No. C2A03333. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that: (1) Pictorial diagram & clear instruction for application of drug product in disease area shall be provided to patients (2) Each patient's, photograph of treatment area shall be taken at the baseline & end of study.
3.	CT/168/23 Online Submission (41129) Dated 22/12/2023 Bedaquiline [JNJ-16175328] Rifampicin Clofazimine Dapsone	M/s Johnson & Johnson Pvt. Ltd.	The firm presented Phase III clinical study protocol No. TMC207LEP3001. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition to include more than 5 skin lesions which are smear positive in inclusion criteria.
Biological Division			
4.	BIO/CT04/FF/2023/39138 Dupilimumab 150mg/mL solution for injection	M/s. Sanofi Healthcare Pt. Ltd	The firm presented Phase IV clinical trial protocol titled "A multi-center, single-arm phase IV clinical trial to evaluate the safety of Dupilumab in adult Indian patients with moderate to severe atopic dermatitis" vide protocol number LPS18048 version number: FINAL version 1.1 Date: 2 AUG 2023 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the phase IV clinical trial as

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			presented by the firm.
FDC Division			
5.	FDC/CT/23/000074 Test formulation A: Dutasteride 0.05 % w/w + Minoxidil 5 % w/w & Test formulation B: Dutasteride 0.05 % w/w Latanoprost 0.03 % w/w Topical Solution	M/s Glenmark Pharmaceuticals Ltd.	In the light of earlier SEC recommendation dated 12.12.2023, the firm presented their proposal along with revised Phase II clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II clinical trial as per the revised protocol. The firm should submit Phase II clinical trial report to CDSCO for further review by the committee.