Recommendations of the SEC (Dermatology & Allergy) made in its 02nd/24 meeting held on 07.02.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	Online Submission (41581) Rifamycin 1% Topical Solution	M/s. Spinos Lifescience	The firm has presented phase III clinical trial protocol No. SLS-CT-0005-23-RIFA, version No. 01 dated 04/ November/ 23. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that study duration shall be 45 days and dropout rate shall be 20 percent. Accordingly, revised protocol shall be submitted to CDSCO by firm.
Biological Division			
2.	BIO/CT04/FF/2023/37764 Ustekinumab injection 45mg/0.5ml	M/s. Biocon	The firm presented the proposal to conduct PK/PD study titled "A phase I, randomized, open-label, 2-arm, parallel design study in normal healthy subjects to evaluate pharmacokinetics, safety, and tolerability of Bmab 1200 -autoinjector (biosimilar Ustekinumab) after single subcutaneous injection in comparison with Bmab 1200 -prefilled syringe (biosimilar Ustekinumab)" vide protocol version 1.0, dated 17.05.2023. After detailed deliberation, the committee recommended to conduct the study as per the protocol presented by the firm.
3.	E-receipt no. 5803 Human epidermal growth factor (r-hu EGF) topical gel	M/s. Bharat Biotech	The firm presented the proposal for modification in the approved indication. After detailed deliberation, the committee recommended to modify the approved indication as follows: Indicated for the first and second-degree burn wounds, for healing of donor site skin graft area.
BA/BE Division			
4.	File No. 12-09/2024/BA-BE/MISC-08/DC BABE/CT05/FF/2023/40000 Isotretinoin Capsules	M/s. Aurobindo Pharma Ltd, Hyderabad-500038	The firm presented the protocol No.239-23 version 1 and 240-23 version 1 dated 22-9-2023 before the committee. After detailed deliberation, the committee recommended for following changes in the protocol:

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	USP 60 mg		1-BMI range 2-Increase in sample size with consideration of drop out percentage. Accordingly, the firm shall submit the revised protocol to CDSCO for further deliberation before the committee.
SND Division			
5.	SND/MA/23/000285 Biotin tablets 10000mcg	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented the proposal for grant of permission to manufacture and marketing of Biotin 10,000mcg tablets along with justification for waiver of local clinical trial and Bioequivalence study before the committee. The firm has informed that individually Biotin 10,000mcg tablets is not yet approved anywhere. After detailed deliberation, the committee opined that the firm should submit clinical justification of proposed formulation along with more clinical safety & efficacy data including evidence of adverse effect with high dose to CDSCO for further review by the committee.
6.	SND/MA/23/000291 Dutasteride capsules IP 0.5mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented the proposal for grant of permission to manufacture and marketing of Dutasteride capsules 0.5mg along with justification for waiver of local clinical trial and Bioequivalence study before the Committee. The firm has informed that proposed drug Dutasteride capsules 0.5mg has been approved BPH in year 2004, However, for Androgenic Alopecia (AGA) approved in Japan (Year 2015) and South Korea (Year 2010) only. After detailed deliberation, the committee opined that the firm should submit safety data for Dutasteride for proposed indication and this proposal should be deliberated in presence of Urologist.
New Drug Division			
7.	ND/MA/22/000057 Fosravuconazole L-Lysine Ethanolate Capsule 169.1mg	M/s. Dr. Reddy's	The firm presented their proposal for revising Phase-III clinical protocol from DRL-IND-NDA04-FOS/2022, version 1.0 to DRL-IND-NDA04-FOS/2022,

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			version 2.0 Date: 11-October-2023 before the committee. After detailed deliberation, the committee recommended for grant of permission for the proposed protocol subject to the condition that the firm to reassess the calculation of sample size.