Recommendations of the SEC (Dermatology & Allergy) made in its 62nd meeting held on 13.10.2021 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drugs Division			
1.	12-01/18-DC(Pt.337) Betamethasone induced Photosensitivity reaction	Internal Discussion	The proposal of the PvPI along with the recommendation related to Betamethasone induced ADRs was discussed by the committee. Committee noted that the misuse of steroids such as Betamethasone ointment formulations over the face is associated with the sensitive skin–Topical Steroid Dependent Facies (Which may induce photosensitivity) and rarely contact allergy with photosensitivity. After detailed deliberation, the committee opined that more data may be obtained from PvPI, IPC in support of the ADR-betamethasone induced photosensitivity.
Subsequent New Drugs Division			
2.	12-82/2017-DC (Pt-Cadila-SND) Calcipotriol/AKVANO 50ug/gm cutaneous solution	M/s Cadila Pharmaceuticals	The firm did not turn up for the presentation.
3.	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 meeting held on 12/08/2021, the firm presented the justification for the indication for use of the drug in skin ulcer. After deliberation, the committee opined that firm should submit the supportive data on activity of Biopolymer used in the product and submit the revised clinical trial protocol to CDSCO for review by the committee.

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4.	SND/MA/21/000448 ALDP001	M/s Alkem Laboratories	The firm presented their proposal along with protocol for conduct of Phase 0 Single dose study to evaluate the pharmacokinetics of ALDP001 (0.125%) administration by intranasal route in healthy adult human subjects, Phase I single ascending dose study, single dose comparative bioavailability study of ALDP001 (Nasal Spray 0.5%) with Alcaftadine ophthalmic solution 0.25% and Phase I multiple ascending dose study. After detailed deliberation, committee recommended for grant of permission to conduct the clinical studies as per the protocol presented by the firm. Accordingly, the firm should submit the results of the studies for further deliberation in SEC in presence of ENT expert.
5.	SND/MA/20/000198 Itraconazole Capsule 100mg	M/s. Intas Pharma	In light of earlier recommendation of SEC meeting held on 14/09/2021, the firm presented updated package insert. After detailed deliberation, the committee opined that the package insert should be revised mentioning the effect of proton pump inhibitors, oral antacids, alcohol etc. that affect the bioavailability of the drug. Accordingly the firm should submit revised package insert to CDSCO for further consideration.
6.	12-124/2017-DC (Pt-Novalead-SND) Esmolol Hydrochloride gel 14.00 % w/w	M/s. Novalead Pharma	In light of earlier SEC recommendations held on 15.04.2021, the firm presented analysed data of the completed subjects & presented the results of Phase III Clinical trial of Esmolol Hydrochloride 14.00%w/w for Diabetic foot ulcers (DFU). The committee noted that as per the protocol approved by SEC, patients with superficial ulcer should be recruited. However, it was observed that some cases with deep ulcer were also included in the study. After detailed deliberation, the committee recommended that the firm should repeat the study with well-defined criteria for choosing the superficial ulcers.

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FDC Division			
7.	FDC/MA/21/000155 Clindamycin phosphate 1.2% USP + Benzoyl peroxide 5% USP topical gel	M/s. Encube Ethicals Pvt. Ltd.	The firm presented their proposal along with clinical trial report before the committee. The committee noted that the proposed FDC is already approved in US. After detailed deliberation, the Committee recommended for grant of permission for manufacturing and marketing the proposed higher strength with the condition that Phase IV trial shall be conducted keeping safety as primary objective. Accordingly, the trial protocol shall be submitted within 3 months of approval of the product.
GCT Division			
8.	CT/91/18 Online Submission (11989) Secukinumab	M/s. Novartis	The firm presented their proposal for protocol amendment 2 dated 08 Jan 2021 before the committee. After detailed deliberation the committee recommended for approval of the proposed protocol amendment 2 dated 08 Jan 2021.
9.	CT /5719 Online Submission (12822) Dated 06/10/21 Baricitinib	M/s. Eli Lilly	In light of earlier SEC recommendations held on 05.11.2019, the firm presented their proposal for inclusion of lower age group (2 to 11years of age) before the committee. The firm presented Safety and Tolerability results for PK Lead-in patients 10 to <18 years old (N-20), 05 cases of headache noted in the age group. However, cause of headache not assessed. After detailed deliberation, the committee opined that for safety point of view, atleast 25 subjects should be enrolled in double blind study with age group of 12-18 years from India. The committee also opined that the firm should submit the following for further review: 1. Cause of headache reported in 5 subjects. 2. DSMB recommendation letter regarding continuation of the trial.

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Medical Device Division			
10.	CI/MD/2021/38809 Ablation Device Cryotherapy	BIBAWO MEDICAL PRIVATE LTD	The firm presented the revised protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the Phase IV clinical Investigation with the revised protocol. The report of clinical investigation shall be submitted to CDSCO for expert review.