Recommendations of the SEC (Dermatology & Allergy) made in its 60th meeting held on 12.08.2021 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	12-01/18-DC(Pt-337) Cetrizine tablet	SRP/PvPI	The committee after detailed deliberation recommended that more data may be obtained from PVPI.
Biological Division			
2.	BIO/IMP/21/000046	M/s. Sun Pharmaceuticals Industries Limited	The firm presented proposal for grant of marketing authorization of the drug along with clinical data generated in other countries and requested waiver of local Clinical Trial. After detailed deliberation, the committee recommended that the firm should submit safety and efficacy data of the drug in Indian population for further consideration.
SND Division			
3.	SND/MA/21/0003111 Minoxidil Topical Solution 2% and Minoxidil Topical solution 5%.	M/s Dr. Reddy's laboratories	The firm presented their proposal for manufacturing and marketing of Minoxidil Topical Solution 2% & 5% for the treatment of androgenic alopecia in female with female pattern baldness with request of Clinical Trial waiver. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Minoxidil Topical Solution 2% & 5% for the treatment of androgenic alopecia in females (female pattern hair loss).
4.	12-130/2016-DC (Pt-Galderma-SND) Clostridium Botulinum type A toxin Haemagglutinin complex injection 300 units/vial (Intramuscular Injection)	M/s Galderma India	The firm has presented the Phase IV clinical trial report before the committee. After detailed deliberation the committee noted the results of the Phase IV clinical trial presented by the firm.
5.	SND/MA/21/00304 Ozenoxacin Lotion 2%w/v	M/s Precise Biopharma	In light of earlier SEC recommendations dated 08.07.2021, the firm presented revised Phase III Clinical Trial Protocol of Ozenoxacin Lotion 2%w/v. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III CT Study as per the protocol presented.

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6.	SND/IMP/21/00001 Baricitinib tablets 2/4mg	M/s. Eli-Lilly	In light of recommendations of earlier committee meeting held on 09.06.2021. the firm presented their proposal for reconsideration of clinical trial waiver. After detailed deliberation, the committee re-iterated its earlier recommendations that "the firm should conduct a clinical study on clinically significant number of patients by excluding the patients with past history or on concurrent TB. Further, photographs should be documented during the conduct of the study. Accordingly, the firm should submit the Phase III clinical trial protocol to CDSCO for review by the committee".
7.	SND/CT/21/00052 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	The firm presented the proposal of Mupirocin 2.0% w/w in an ointment base containing Biopolymer: Poly-β-(1-4)-2 amino-2 deoxy-d-glucose (Chitosan) along with the Clinical trial protocol before the committee. After detailed deliberation the committee opined that the firm should submit scientific basis for development of the proposed product for proposed additional indication in skin ulcers.
8.	SND/MA/21/00027 Itraconazole Capsules 100 mg (SB)	M/s. Macloeds Pharma	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the BE study as per protocol presented.
FDC Division			
9.	FDC/MA/21/000151 Clotrimazole USP 10mg + Betamethasone Dipropionate USP 0.643 mg topical cream	Glenmark Pharmaceuticals Ltd.	The firm presented their proposal before the committee. Committee noted that, the permission for conducting the clinical trial was granted to the firm in 2008 as a part of global clinical trial which is not of much relevance in current scenario. Therefore, the committee recommended that the firm should conduct Phase III clinical trial comparing its product with the Clotrimazole alone with longer follow up period. Accordingly Phase III clinical study protocol should be submitted covering all the applied indications, for further deliberation before the committee.
10.	FDC/MA/21/000152 Calcipotriene 0.005% + Betamethasone	Glenmark Pharmaceuticals Ltd.	The firm presented the proposal before the committee along with Phase III data generated in US. Committee noted that the

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	dipropionate 0.064% topical suspension		firm has not conducted Phase III clinical trial in India. After detailed deliberation, committee recommended that the firm should conduct Phase III clinical trial in Indian patients and accordingly Phase III CT protocol should be submitted for further review by the committee.
Medical Device Division			
11.	CI/MD/2021/38809 Ablation Device Cryotherapy (HYDROZID)	Bibawo Medical private ltd	The firm presented their protocol for post market clinical investigation before the committee. After detailed deliberation, the committee recommended grant of permission to conduct the post market clinical investigation subject to condition that: 1. Sample size should be increased from 50 to 100. 2. Number of clinical sites should be increased from 2 to 4. 3. Size of lesions should be 5mm to 10mm instead of 5mm to 20mm. 4. The firm shall use the validated scale for measurement of scar. 5. Follow up should be upto 60th day instead of 40 days and all parameters should be measured at 60th day. Accordingly, the firm needs to revise the protocol for the review by the committee.