Recommendations of the SEC (Dermatology & Allergy) made in its 56th meeting held on 16.03.2021at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000096 Ozenoxacin Cream 1% w/w	M/s Om Sai pharma	The firm presented Phase-III Clinical trial report with proposal for grant of permission to manufacture and market the drug Ozenoxacin Cream1%. The drug is already approved in other countries like USA since 2017. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug in the country with condition that the drug should be sold by retail on prescription of "specialist" only.
2.	ND/MA/21/000028 Ozenoxacin Cream 1% w/w	M/s Optimus Pvt. Ltd	The firm presented their proposal for conduct of phase III clinical trial with the protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented.
SND Division			
3.	SND/MA/21/000013 Tazarotene Lotion 0.045%	M/s Glenmark Pharma	The firm presented their proposal for Tazarotene Lotion 0.045% before the committee. The committee noted that the product is already approved internationally for past several years. Tazarotene Cream and Gel 0.05% has been approved in India for many years. After detailed deliberation the committee recommended for grant of permission for manufacture and marketing of the drug product Tazarotene Lotion 0.045% for use in treatment of Acne.
4.	SND/MA/20/000377 Minocycline hydrochloride topical Gel 4 %	M/s Glenmark Pharma	Firm didn't turn up for presentation.
FDC Division			

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5.	FDC/MA/20/000161 Alcohol IP eq to absolute alcohol +Minoxidil (40 v/v+10 % w/v)Topical Solution	M/s Pure &Cure Healthcare Pvt Ltd.	Firm did not turn up for the presentation.
6.	FDC/MA/20/000162 Beclomethasonedipropionate 0.0250 %w/w IP +Luliconazole 1.0000 w/w cream	M/s Malik Life sciences Pvt Ltd	In light of the earlier SEC recommendation dated 10.12.2020, firm presented their proposal along with revised Phase III Clinical trial protocol. Committee opined that, the revised Phase III Clinical trial protocol appears to be satisfactory. The Committee suggested that Photographic evidence should be included in the trial protocol. However, firm did not present the Dermal Toxicity study results of the proposed FDC. The Committee recommended that the firm should present the dermal toxicity results as per the requirements before grant of permission for conducting the Phase III clinical trial.
7.	FDC/CT/21/000015 Betamethasone dipropionateEP+Calcipotriol anhydrous mcg EP (0.6430mg+50mcg) cutaneous spray	M/s Cadila Pharmaceutical Ltd.	The firm presented their proposal along with the Phase III Clinical Trial protocol before the committee. The Committee noted that the proposed trial is for submission of data to EU. After detailed deliberation, the committee recommended that 1. Quantification of quantum of hair should be incorporated in the inclusion criteria. 2. Photographic evidence should be included in the protocol. 3. More government sites should be included in the study. Accordingly, the Committee recommended that firm should submit revised trial protocol along with Dermal toxicity study report for further review by the committee.
GCT Division			
8.	CT/57/19/Online submission 10108 Baricitinib	M/s. Eli Lilly	The firm presented the protocol amendment I4V-MC-JAIP(b) dated 06-08-2020 and compared with the earlier protocol I4V-MC-JAIP(a) dated 12-06-2019 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment.

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Medical Device Division			
9.	IMP/MD/2019/13613 Farmactive silver spray	M/s Bryogen Pharmaceuticals Private Limited	In light of earlier SEC recommendation dated 13.07.2020 and 05.10.2020, firm presented their proposal before the committee along with updated clinical evaluation data. After detailed deliberation, committee recommended for grant of permission to import and market the product for use on clean fresh wound only; with the condition that firm should conduct phase IV clinical investigation. Accordingly firm should submit revised IFU andclinical trial protocol within 3 months from the date of approval.
10.	IMP/MD/2020/27740 Soft –adherent foam dressing with TLC-NOSF	M/s Eucare pharmaceuticals private Ltd	In light of earlier SEC recommendation dated 05.10.2020 and 12.11.2020, firm presented their proposal before the committee along with updated clinical evaluation data. After detailed deliberation, committee recommended for the grant of permission to import and market the product for indication of non-healing, oozing wounds and ulcers. Accordingly firm should submit revised IFU and also firm needs to submit PSUR in every six months from the date of approval.
11.	MD/Post/Appr/2020/3688 Hyaluronic acid 20mg /ml	M/s Galderma India Pvt Ltd	Firm presented their proposal before the committee for extended intended use. After detailed deliberation the committee recommended for grant of Post Approval Change subject to condition that the firm shall submit the regulatory approval from the NRA of Sweden.
12.	IMP/MD/2019/14121 IFABOND	M/s Peter surgical	In light of earlier SEC recommendation dated 13.07.2020 and 12.11.2020, the firm presented their proposal before the committee with published clinical data. After detailed deliberation, committee observed that the published safety and efficacy data presented by the firm was not adequate in order to establish the safety and efficacy of the product. Further, the proposal needs to be consulted with endoscopy and gynecology surgeons

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			as per indications claimed. The committee also felt that the presenter should be a user expert in order to explain the safety and efficacy data. The proposal may be deliberated in next SEC meeting along with endoscopy and gynecology surgeon as special invitee.