Recommendations of the SEC (Dermatology & Allergy) made in its 59th meeting held on 08.07.2021 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/220/00051 Bilastine Tablet 40 mg	M/s Synokem	Earlier the firm had already presented the BE study report and now the firm presented the proposal along with Phase III CT study report. After detailed deliberation the committee recommended for grant of permission to manufacture and market Bilastine Tablet 40 mg as additional strength indicated for the treatment of chronic spontaneous urticaria subject to condition that the firm should conduct active PMS study. Accordingly, submit protocol for the review by the committee.
2.	SND/MA/21/000304 Ozenoxacin Lotion 2%w/v	M/s Precise BiopharmaPvt Ltd	The firm presented proposal for manufacturing and marketing of Ozenoxacin Lotion 2.0% along with Phase III Clinical trial protocol. After detailed deliberation the committee recommended for changes in protocol as follow:- 1.Include one more arm which is Standard of Care 2. In inclusion criteria exclude the Grade IV Acne 3. Include the details of rescue medications. Accordingly, the firm should submit revised protocol for further consideration by committee.
3.	SND/MA/20/000107 Amorolfine Lotion 0.25%	M/s. Zydus Healthcare	The firm presented proposal for manufacturing and marketing of Amorolfine Lotion 0.25%along with the results of the Phase III clinical trial. After detailed deliberation committee recommended for grantof permission to manufacture and market Amorolfine Lotion 0.25% for the treatment of dermatomycosis caused by dermatophytes, cutaneous candidiasis and pitryriasis versicolor.
4.	12-160/2017-DC (Pt-Glenmark-snd) Apremilast 10/20/30 mg tablets	M/s. Glenmark	The firm presented interim results of the Phase IV clinical trial before the committee and requested for early closure of the study. Committee noted that the permission for manufacturing and marketing was granted with the condition to conduct the Phase IV

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			clinical trial. After detailed deliberation committee recommended that firm request for early closure cannot be considered based on the data presented.
Medical Device Division			
5.	IMP/MD/2019/14121 IFABOND	M/s Peter Surgical	In light of earlier SEC recommendations dated 16.03.2021,the firm presented their proposal before the committee alongwith clinical and preclinical data. After detailed deliberation the committee recommended for grant of permission to import and market the product in the country subject to the condition that the firm shall conduct Phase IV clinical investigation in the country for which the protocol needs to be submitted to CDSCO within 4 months from the date of licensing for further review by the committee.
6.	CI/MD/2021/35339 Absorbable Hemostat	M/s. Scitus Pharma Service Pvt. Ltd.	In light of earlier SEC recommendations dated 09.06.2021, the firm presented their revised protocol for Phase III pivotal clinical investigation before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the clinical investigation in the country subjected to following conditions: 1. Indication of the product should be on light to moderate blood ooze from the wounds after taking care of the arterial, venous, capillary bleeding. 2. The firm should indicate in the protocol type of surgeries and as far as possible same type of surgeries should be adopted in referenced product.
BA/BE Division			
7.	12-09/2021/BA-BE/MISC-12/DC Tretinoin Cream 0.1 %	M/s. Catawba Research India Private Limited, Mumbai.	The firm presented proposal for conduct of clinical end point BE study for export registration. After detailed deliberation Committee observed that the study design is as per USFDA OGD recommendation and hence, recommended grant of permission to conduct the proposed clinical end point BE study for export registration purpose subject to the condition that rescue

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			medication shall be given to the patients in the placebo control group in case of any exacerbation of symptoms occurs. Hence, standard treatment protocol for rescue medication shall be submitted before initiation of the study.
8.	12-09/2021/BA-BE/MISC-13/DC Adapalene Gel, 0.3%	M/s. Invitro Research Solutions Private Limited, Bangalore-560024	The firm presented proposal for conduct of clinical end point BE study for export registration. After detailed deliberation Committee observed that the study design is as per USFDA OGD recommendation and hence, recommended grant of permission to conduct the proposed clinical end point BE study for export registration purpose subject to the condition that rescue medication shall be given to the patients in the placebo control group in case of any exacerbation of symptoms occurs. Hence, standard treatment protocol for rescue medication shall be submitted before initiation of the study.