Recommendations of the SEC (Dermatology & Allergy) made in its 46th meeting held on 19.06.2020 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/CT/20/000003 Clotrimazole 10mg+Gentamicin sulfate 1mg+Betamethasone dipropionate 0.64mg creams	M/s. Agio Pharmaceuticals Ltd.	The firm presented their phase III clinical trial protocol for export purpose before the committee. After detailed deliberation the committee opined that the protocol is deficient in respect of following: 1. Percentage of affected area of the body on which the product will be applied during the trial is not defined. 2. Treatment duration should not be more than 15 days. 3. Patients with the evidence of fungal and bacterial infection should only be included. Inclusion and exclusion criteria needs to be revised accordingly. Accordingly, the committee recommended that the firm should revise and submit the Clinical Trial protocol for further review.
Subsequent New Drug Division			
2.	SND/MA/18/000074 Itraconazole oral solution 10mg/ml	M/s Synokem	In light of earlier SEC recommendation dated 02.09.2019, the firm presented BE study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the Itraconazole oral solution 10mg/ml.
3.	SND/MA/20/00051 Bilastine 40 mg Tablet	M/s Synokem	The firm presented the proposal along with the protocol for Be study and Phase III clinical trial. After detailed deliberation the committee recommended for grant of permission for conduct of the BE study as per the protocol presented. However, the Phase III clinical trial protocol should be revised to make it a three arm study of Bilastine tablet 40mg vs. Bilastine tablet 20mg vs. Levocetirizine tablets 10 mg. Accordingly; the firm should submit the revised CT protocol along with justification for sample size to CDSCO for approval. The BE study report should be submitted to CDSCO prior to initiation

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			of the clinical trial.
4.	SND/MA/18/000093 Itraconazole 50 mg capsules	M/s Intas	The firm presented the proposal along with the BE study report of itraconazole Capsules 50mg. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Itraconazole Capsules 50mg with the caution in the Package insert as follows: "Caution: Itraconazole Capsules 50mg has equivalent bioavailability with that of itraconazole capsules 100mg. One capsule of Itraconazole Capsule 50mg is therapeutically equivalent to one 100mg capsule of conventional itraconazole capsules100mg. The recommended dose of itraconazole Capsules 50mg is therefore half the recommended dose for conventional itraconazole capsules 100 mg. Itraconazole Capsules 50mg and conventional itraconazole Capsules 100mg are not interchangeable".
5.	SND/MA/19/000206 Bilastine Orodispersible tablet 10mg	M/s Akums	In light of earlier SEC recommendation dated 17.01.2020, the firm presented BE study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the Bilastine Orodispersible tablet 10mg.
6.	SND/MA/19/000077 Dehydrated Human amnion/chorion tissue allografts (dHACM)	M/s Life Cell	In light of earlier SEC recommendation dated 05/11/2019, the firm presented the animal study report along with photographs of the wounds before and after the treatment. After detailed deliberation, the committee recommended that the firm should conduct a Phase III clinical trial in wounds of size 5 cm or more. Accordingly, the firm should submit the protocol for review by the committee
7.	SND/MA/20/000094 Isotretinoin capsules 8mg/16mg/24mg	M/s Sun pharma	The firm presented the proposal along with the BE study report of micronized isotretinoin capsules 24mg. After detailed deliberation the

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			committee recommended that the firm should submit human safety data of micronized Isotretinoin formulation to consider the matter further.
GCT Division			
8.	CT/20/20 Online Submission (18919) Dated 09/03/20 Secukinumab	M/s Novartis	Applicant presented their proposal for Phase III extension clinical trial with the protocol before the committee. After detailed deliberation, the committee recommended that the firm should submit the safety data of the product from the ongoing study for review by the committee to consider the matter further
9.	CT/32/20 Online Submission (19129) Dated 10/04/20 Natroba	M/s Scitus Pharma	Applicant presented their Phase III clinical trial study protocol before the committee. After detailed deliberation, the committee recommended that the firm should submit the detailed safety data of the product for review by the committee to consider the matter further.
10.	CT/38/20 Online Submission (19370) Dated 24/04/20 Ligelizumab	M/s Novartis	Applicant presented their proposal for Phase III extension clinical trial along with the protocol before the committee. After detailed deliberation, the committee recommended that the firm should submit safety data from the ongoing trial for review by the committee to consider the matter further.
New Drug Division			
11.	ND/CT-21/FF/2019/17528 Naftifine Hcl Gel USP 2%	M/s Hetero Labs Limited	Applicant presented their proposal along with clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial.