Recommendations of the SEC (Dermatology & Allergy) made in its 33rd meeting held on 13.09.2018 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
New Drugs Division			
1	12-01/18-DC (Pt 143) Cyclosporine	Prof. Kaushal K. Verma, Department of Dermatology &Venereology, AIIMS, New Delhi	Prof. Verma presented the proposal as an academic clinical trial. After detailed deliberation, the committee recommended that detailed presentation with justification for the proposed study design including outcome/ evaluation methodology should be made for further consideration. **Dr. Binod Khaitan did not participate in the deliberation.**
BA/BE Division			
2	12-09/2018/BA-BE/Misc-23/DC Protopic® (tacrolimus) ointment, 0.1%	M/s. ENCUBE ETHICALS PVT. LTD	As per recommendation of the Committee made in it's earlier meeting held on 26.07.2018, the firm presented the revised protocol for the BE study based on therapeutic end point, with respect to criteria for defining the disease, scoring the severity of disease, inclusion & exclusion criteria, safety & efficacy criteria etc. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study.
3	12-09/2018/BA-BE/Misc-24/DC Elidel® (Pimecrolimus) Cream 1%	M/s. ENCUBE ETHICALS PVT. LTD	As per recommendation of the Committee made in it's earlier meeting held on 26.07.2018, the firm presented the revised protocol for the BE study based on therapeutic end point, with respect to criteria for defining the disease, scoring the severity of disease, inclusion & exclusion criteria, safety & efficacy criteria etc. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study.
Medical Device Division			
4	MFG/MP_MD/2018/2639 PRINCESS VOLUME LIDOCAINE 2.3% Highly Crosslinked Sodium Hyaluronate + 0.3% Lidocaine HCL	M/s. Accredited Consultants Pvt. Ltd.,	Firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm should make detailed presentation on the product including the details of crosslinking, clearance data of lidocaine, indications, contraindications, adverse effects speciallyin

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
			elderly/cardiac patients, global PMS data and plan for PMS in India for further consideration.
5	MFG/MP_MD/2018/2635 PRINCESS FILLER LIDOCAINE 2.3% Hyaluronic Acid + 0.3% Lidocaine HCL	M/s. Accredited Consultants Pvt. Ltd.,	Firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm should make detailed presentation on the product including the details of crosslinking, clearance data of lidocaine, indications, contraindications, adverse effects specially in elderly/cardiac patients, global PMS data and plan for PMS in India for further consideration.
Global Clinical Trials Division			
6	CT/45/18 Ligelizumab	M/s Novartis	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** To demonstrate that ligelizumab (72 mg q4w and/or 120 mg q4w) is superior to placebo and superior to omalizumab 300 mg q4w in change from baseline in UAS7 at Week 12. **Unmet Medical Need in the country:** The test drug may potentially provide alternate treatment option in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study.
7	CT/46/18 Ligelizumab	M/s Novartis	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** To demonstrate that ligelizumab (72 mg q4w and/or 120 mg q4w) is superior to placebo and superior to omalizumab 300 mg q4w in change from baseline in UAS7at Week 12. **Unmet Medical Need in the country:** The test drug may potentially provide alternate treatment option in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study.
8	CT/49/18 Itraconazole	M/s J&J	The firm didn't turn up for presentation.
9	CT/55/18 Nexobrid	M/s Apothecaries	**Risk versus benefit to the patients-** The safety profile of the investigator drug from various pre-clinical studies including systemic toxicity studies, repeat dose, genotoxicity, carcinogenicity, reproductive studies and clinical studies justify the conduct of the study. **Innovation vis-a-vis existing therapeutic-** The purpose of the study to demonstrate enzymatic eschar removal efficacy of NexoBrid by providing earlier, complete eschar removal. • To demonstrate enzymatic eschar removal efficacy of NexoBrid by reducing patients' surgical burden and resulting in non-inferior final outcomes of cosmesis and function as compared to SOC. • To assess the safety of NexoBrid compared to SOC **Unmet medical need in the country-** The test drug may potentially provide treatment in children with thermal burns. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study.
10	CT/56/18 Adapalene (0.3%) +Benzoyl peroxide (2.5%)	M/s Cliantha	**Assessment of risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity, genotoxicity, reproductive, carcinogenicity, Phase I and Phase II clinical study justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** The Purpose of the study to Evaluate the Bioequivalence (with clinical endpoint) of Adapalene and Benzoyl Peroxide Gel, 0.3%/2.5% (Cadila Healthcare Ltd, India) to EPIDUO® FORTE (Adapalene and Benzoyl Peroxide) Gel, 0.3%/2.5% (Galderma Laboratories, L.P., USA) in subjects with Acne Vulgaris. **Unmet Medical need in the country:** The

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
			test drug may potentially provide treatment in with Acne Vulgaris. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study.