Recommendations of the SEC meeting to examine IND proposals, made in its 5th meeting held on 28.08.2020 at CDSCO, HQ New Delhi, through Webex (Videoconference):

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	12-107/88-DC RISUG	M/s. Icu BeD G Ideas Pvt. Ltd.	The applicant presented their RISUG reversibility clinical trial protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the proposed clinical trial, subject to conditions that, following information should be submitted to CDSCO, before initiation of the clinical trial: 1. Freshly recruited subjects for reversibility should be divided into two parts, one part for assessment after nine months of RISUG injection and other part should be assessed after 18 months of RISUG injection. 2. The subject should be followed up for nine months for reversibility assessment. 3. Serum FSH level should be assessed in all the subjects. 4. Proper justification for sample size should be submitted. 5. Appropriate advice regarding contraceptives measures required to be provided to the subjects should be specified in the protocol. 6. Detailed justification for use of 100% DMSO in the formulation. Dr. Monika Pahuja & Dr. J. J. Cherian did not participate in the deliberation.
2.	IND/CT04/FF/2020/20942 HRF-10071	M/s. Lambda	The firm presented their proposal to conduct the Phase I Clinical Trial before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the Clinical trial subject to the following conditions: 1. In SAD study, after completion of 80mg cohort, the interim results

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
			should be submitted to CDSCO. 2. The results of SAD study including the report from DSMB should be submitted for review by the committee before proceeding to MAD study.
3.	IND/CT/20/000057 IND/CT04/FF/2020/20946 ISC 17536	M/s. Glenmark	The firm presented their proposal to conduct the Phase I Clinical Trial before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the proposed clinical trial.
4.	IND/CT04/2020 IND/CT/20/000059 Desidustat	M/s. Cadila	The firm presented their proposal to conduct Phase I Clinical Trial before the committee. The committee opined that the subject drug is under clinical trial for different indication. After detailed deliberation the committee recommended for grant of permission to conduct the proposed clinical trial.