Recommendations of the SEC meeting to examine IND proposals, made in its 11th meeting held on 08.03.2021 at CDSCO, HQ New Delhi, through Webex (Video conference):

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	F. No. ND/CT/21/000014 Endoxifen tablets 8mg	M/s Intas Pharmaceuticals Ltd	The firm presented the Phase IV Clinical trial protocol for the drug before the committee. After detailed deliberation, the committee recommended that the firm should submit the following: 1. Sample size should be recalculated along with the justification based on the primary safety endpoint. 2. Safety concern from the earlier published study. 3. Detailed adverse drug reactions after the causality assessment adopting WHO scale. 4. Additional pregnancy test should be performed at the start of the therapy in Women of child bearing potential (WOCBP). 5. Estimation of GFR to be included in inclusion criteria. Accordingly, the firm should submit the revised protocol to CDSCO within one month for further consideration.
2.	F. No. IND/CT/21/000001 AUR101	M/s Aurigene Discovery Technologies Limited	The firm presented their proposal for conduct of Phase II Clinical trial before the committee. After detailed deliberation the committee recommended that the firm should include standard of care arm in the trial. Further, the committee opined that the firm should include a dermatologist in the trial and justification for giving OD dose should be submitted. Further, the committee opined that the proposal should be deliberated in the next meeting along with dermatologist.

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			Accordingly, the firm should submit the revised protocol to CDSCO for further consideration.
3.	F. No. IND/CT/20/000004004 CA 170	M/s Aurigene Discovery Technologies Limited	The firm presented amendment in the protocol before the committee. After detailed deliberation, the committee carefully considered the request of the firm and did not recommend for the amendment in the clinical trial protocol.
4.	F. No. IND/CT/18/000002 HRF-4467 solution 20mg/ml	M/s Hetero Labs Limited	The firm didn't turn up for the presentation.
5.	F. No. 12-107/88-DC RISUG Male Contraceptive	M/s Icubed G Ideas Pvt Ltd, New Delhi	The firm presented detailed project report of RISUG before the committee. The committee recommended that further action may be taken as per the recommendations of IND meeting dt 10.10.2019 wherein the committee had recommended for the grant of permission for manufacturing and marketing of the product subject to fulfillment of various conditions.
6.	F. No. IND/CT/21/000004 NCE MSP008-22	M/s Clinexel Life Sciences Pvt. Ltd	The firm presented their Phase I Clinical trial protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the Phase I clinical trial subject to the condition that the firm should submit the DSMB report before the dose escalation to CDSCO for further consideration.
7.	F. No. IND/CT/18/000001 Nafithromycin,	M/s Wockhardt Ltd	The firm presented their proposal for amendment in the clinical trial protocol before the committee. After detailed deliberation the committee recommended for approval of the

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	WCK-4873		proposal for amendment in protocol as submitted by the firm.
8.	F. No. IND/CT/18/000003 CPL 2009-0031	M/s Cadila Pharmaceuticals	The firm presented their Phase-III Clinical trial report before the committee. After detailed deliberation the committee recommended that the firm should submit separate application for manufacturing & marketing of the product along with Preclinical, Phase I, Phase II & Phase III clinical trial data an present the same before the committee for further deliberation.