Recommendations of the SEC meeting to examine IND proposals, made in its 16th meeting held on 30.09.2021 at CDSCO, HQ New Delhi, through Webex (Videoconference):

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	F. No. 12-02/21-DC PDP-117 Phyto pharmaceutical Tablets	M/s Emami Ltd, Kolkata In collaboration with ICMR	In light of the earlier recommendation dated 17.08.2021, the firm presented their proposal for conduct of Phase-I clinical trial along with CMC data including complete extraction process, characterization of four active compounds, nonclinical regulatory toxicity studies, proof of concept, PK/PD studies, mechanism of action data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-I clinical trial as per the protocol presented subject to the condition that the Insulin and C-peptide should be estimated before and after two weeks of administration of the Investigational product.
2.	F. No. IND/CT/21/000014 MKP 10241	M/s Mankind Research Centre	In light of the earlier recommendation dated 17.08.2021, the firm presented the 28 days repeated dose thymus toxicity data along with OECD-GLP certificate of the test facility before the committee. After detailed deliberation the committee recommended for the approval of the protocol amendment version 01 dated 16.07.2021.
3.	F.No. ND/CT/18/000002 HRF-4467 Solution 20mg/ml	M/s Lambda Therapeutics Ltd	The firm presented the Phase-I clinical trial results before the Committee. The committee noted the results and there is no safety concern reported in the study.