Recommendations of the SEC meeting to examine IND proposals, made in its 17th meeting held on 28.10.2021, 12:00 noon at CDSCO, HQ New Delhi, through Webex (Videoconference):

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	F. No. IND/CT/21/000033 MSP008-22	M/s Clinexel Life Sciences Pvt. Ltd	In light of earlier SEC recommendation held on 19.07.2021, the firm presented the dose response curve and PK data in golden Syrian hamster. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-I clinical trial as per the protocol presented on 19.07.2021 and also opined that after completion of 200mg and 400mg single dose study the firm should submit the data along with the DSMB report for further consideration by the committee.
2.	F. No ND/CT/21/000014 Endoxifen 8 mg Tablets	M/s Intas Pharmaceuticals Ltd.	The firm presented the proposed amendment in Phase-IV clinical trial protocol, before the Committee. After detailed deliberation the committee recommended for grant of approval of the protocol No. 0797-19, amendment version 3.0 dated 17.09.2021 presented by the firm before the committee.