Recommendations of the SEC meeting to examine IND proposals, made in its 26th meeting held on 23.08.2022, 12:00PM at CDSCO, HQ New Delhi, through Webex (Video Conference):

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
1.	F. No IND/CT/22/000058 Desidustat150 mg Tabletsand Rosuvastatin Calcium 10 mg (Drug-Drug Interaction)	M/s Zydus Life Sciences Ltd.,	The firm presented their proposal to conduct clinical trial to study the comparative pharmacokinetic study of Desidustat150 mg and Rosuvastatin Calcium 10 mg before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol subject to the condition that COVID-19 test should be included in the initial screening of the healthy subjects.
2.	File. No. IND/CT/22/000060 Tenofovir Pivafen Fumarate 50mg Tablets	M/s Cipla Ltd.,	The firm presented their proposal to conduct Phase I clinical trial to studySingle Ascending Dose (SAD) and Multiple Ascending Dose (MAD) Study to investigate the Safety, Tolerability, and Pharmacokinetics of Tenofovir Pivafen Fumarate (TPF) and its Metabolites (Tenphenol and Tenofovir) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocols.
3.	F. No. IND/MA/21/000010 2-DG (2-Deoxy-D-Glucose)	Dr. Reddy's Laboratories	The firm did not turn up for meeting.
4.	F. No. IND/CT/22/000043 HRF-10071 120mg Tablets and Darunavir and Ritonavir (Drug-Drug Interaction)	M/s Veeda Clinical Research laboratories	The firm presented the Phase I protocol amendment before the committee for the change in number of subject and additional study objective "To explore the urinary excretion of HRF-10071 under fasting conditions in healthy participants" before the Committee. After detailed deliberation, the committee recommended for grant of approval for the amendment in Phase I clinical trial protocol vide Clinical Study Protocol HCR/I/HRF10071-DRVr/04/2022 Version 02 dated 23 Jul 2022.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	F. No. IND/CT/22/000056 HRF-10071 120mg Tablets and Rifampicin Capsules 600mg (Drug-Drug Interaction)	M/s Synergen Bio Pvt. Ltd.,	The firm presented their proposal to conduct Phase I clinical trial alongwith preclinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.
6.	F. No. IND/CT/22/000057 HRF-10071 120mg Tablets and Metoprolol 100mg/Pravastatin 40mg tablets (Drug-Drug Interaction)	M/s Synergen Bio Pvt. Ltd.,	The firm presented their proposal to conduct Phase I clinical trial alongwith preclinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.
7.	F. No. IND/CT/22/000008 (+)- -DHTBZ 5 mg, 7.5 mg, 10 mg, 15 mg and 22.5 mg powder	M/s Synapse Labs Pvt. Ltd.,	In light of recommendation of the earlier SEC meeting held on 02.08.2022, the firm presented their proposal to conduct Phase I clinical trial protocol along with justification and preclinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.