Recommendations of the SECmeeting to examine COVID-19 related proposalunder accelerated approval process made in its 21th meeting held on 21.03.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/22/000041 Glactomannan 1400 mg Tablets (Prolectin M)	M/s. Murli Krishna Pvt. Ltd.	The firm didn't turn up for presentation.
2.	IND/CT04/22/000005 Umifenovir	M/s. Medizest Pharmaceuticals Pvt. Ltd.	In light of earlier SEC meeting dated 29.07.2021, the firm presented revised Phase III clinical trial protocol, before the committee. After detailed deliberation, the committee recommended that, the firm should revise clinical trial protocol including following: 1. Asymptomatic patients should be excluded from the study. 2. Primary, secondary end point should be revised and clearly defined. 3. Sample size should be in the ratio of 2:1 Umifenovir : Standard of care with 90% confidence interval. 4. Patients of different variants of COVID-19 like Omicrons and Delta should be included in the study. Accordingly, the firm should submit revised protocol to CDSCO for further consideration.
3.	ND/MA/22/000041 Co-Pack of Nirmatrelvir 150 mg and Ritonavir 100 mg Tablet	M/s. Strides	The firm presented proposal for manufacturing and marketing of Co-Pack of Nirmatrelvir 150 mg and Ritonavir 100 mg Tablet along with BE protocol. After detailed deliberation , the committee recommended for grant of permission to conduct the BE study as per the protocol presented by the firm

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
4.	12-01/20-DC(Pt-333) Anti-corona virus therapies	M/s. St. John's, Bangalore	The firm has withdrawn the application.
5.	12-01/20-DC Quercetin	M/s. DIPS,DRDO	The firm didn't turn up for presentation.
GCT Division			
6.	CT/15/21 ATR-002	M/s. Clinexel Life Sciences	In light of earlier SEC recommendation dated 01.12.2021,the firm presented proposal to increase sample size from 40 to 80 from India. After detailed deliberation, committee opined that firm should submit DSMB recommendation, details of Adverse events and Serious adverse events of all recruited subjects for further review by the committee.