

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 226<sup>th</sup> meeting held on 13.05.2022 at CDSCO (HQ), New Delhi:**

<b>Agenda No</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendation</b>
<b>New Drug Division</b>			
1.	ND/MA/22/000041 Co-pack of Nirmatrelvir Tablets 150mg and Ritonavir tablets 100mg	M/s Strides Pharma Science Limited	The firm presented proposal for amendment of BE study protocol before the committee.  After detailed deliberation, the committee recommended for approval for the amendment in the BE protocol as presented.
<b>GCT Division</b>			
2.	CT/119/21 LTX-109	M/s. Parexel	The firm presented protocol amendment Version 3.3 dated 04-Mar-2020 before the committee.  After detailed deliberation, the Committee recommended for approval of the proposed protocol amendment with condition that the trial exclusion criteria No. 6 and 7 should not be removed.
3.	CT/161/21 AZD1222	M/s. IQVIA	In light of earlier SEC recommendation dated 09-02-2022, the firm presented the phase II trial protocol amendment 1, IND-1 dated 31-Mar-2022 before the Committee. After detailed deliberation, the committee opined that the immunogenicity should be co-primary end point for the proposed phase II trial and justification for sample size calculation should be furnished by the firm for further consideration by the committee.
4.	CT/21/000036 (SUGAM#15467) Imatinib Mesylate	M/s. Syngene	The firm presented the proposed protocol amendment Version 3.0 dated 19-Jun-2022 under the phase II trial protocol no. EX003 before the committee. After detailed deliberation, the Committee did not recommend for approval of the proposed amendment, as there is no rationale for the proposed amendment from ARDS due to COVID to ARDS due to pneumonia. Further, the committee suggested that the firm may submit separate trial protocol with the IP for the indication of ARDS due to pneumonia.
5.	CT/15/21 ATR-002	M/s. Clinixel Life Sciences	The firm didn't turn up for presentation.
6.	CT/169/21 INO-4800	M/s Inovio	The firm didn't turn up for presentation.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
<b>FDC Division</b>			
7.	FDC/MA/22/000005  combi kit of Aspirin gastro resistant tablets IP 150mg and Promethazine HCl tablets 5mg & Multivitamin – minerals tablets.	M/s Meyer Vitabiotics	On request of the firm, the proposal was deferred for the next meeting.