Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 121st meeting held on 29.10.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	IND/CT/20/000037 2-Deoxy-D-Glucose oral powder	M/s Dr. Reddy's Laboratories	In light of earlier SEC recommendation dated 13.10.2020, firm presented their proposal for approval of the drug for restricted emergency use and Phase III Clinical Trial protocol before the committee. After detailed deliberation, committee reiterated its earlier recommendation in respect of their proposal and did not recommend for approval of the drug for restricted emergency use as no additional data was presented. As regards Phase III Clinical Trial, committee recommended for grant of permission to conduct Phase III Clinical Trial subject to the following conditions:- 1. 28 days mortality should be included as one of the efficacy end points. 2. If firm intends to perform interim analysis, justification for the same along with detailed statistical plan should be submitted for further review by the committee. 3. The firm should appoint a Medical monitor for co-ordination and monitoring the trial at all the sites.
2.	ND/MA/20/000419 Purified Aqueous extract of Cocculushirsutus tablets 400 mg	M/s Sun Pharma	The firm presented their proposal for approval of the drug for restricted emergency use along with Phase II clinical trial results, before the committee. The committee observed that the trial results have failed to meet the primary efficacy end points. Even in the secondary end point although there was some efficacy in respect of viral

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			clearance in day 7 and median time to clinical improvement, overall clinical data was not satisfactory. Therefore the committee did not recommend for approval of the product for emergency use.
SND Division			
3.	12-01/2020-DC (Pt-NSRT-SND) Eflornithine (Eflornithine Granules 2.5gm & 5.0gm)	M/s NavinSaxena Research & Technology	In light of earlier SEC recommendation dated 13/05/2020 and 01/07/2020, the firm presented the results on PK study & *in-vivo/in-vitro* antiviral activity and some clinical data and requested for approval of drug for emergency use. After detailed deliberation the committee recommended that the data submitted were grossly inadequate and the firm should conduct appropriate phase of Clinical trial. Accordingly, the firm should submit the clinical trial protocol with adequate sample size for review by the committee.
4.	SND/MA/20/000315 for change of regulatory approval status of Remdesivir lyophilised powder for Injection 100 mg	M/s Dr. Reddy's Laboratories	The firm presented the proposal along with clinical data for change in regulatory approval status for Remdesivir Injection from restricted emergency use to full marketing authorisation. After detailed deliberation, the committee did not recommend for grant of full marketing authorisation and opined that approval for Restricted Emergency use of the drug should continue.
5.	SND/CT/20/000054 Remdesivir Injection 100mg/vial	M/s Cadila Healthcare	The firm presented the proposal with Phase IV Clinical trial protocol and Active PMS protocol. After detailed deliberation the committee recommended for grant of permission to conduct of Phase IV CT and Active PMS as per the protocols presented.