Recommendation of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 132nd meeting held on 22.12.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
SND Division			
1.	SND/MA/20/000359 Povidone Iodine nasal solution 0.5%w/v (0.05% available iodine)	M/s Pure & Cure	Firm presented the proposal for marketing authorization of Povidone Iodine Nasal solution 0.5% w/v (0.05% available iodine) for supportive care in mild to moderate COVID -19. However, committee opined that the data presented was not adequate. After detailed deliberation committee did not recommend for approval of the proposed product in COVID-19 due to lack of adequate clinical evidence.
2.	SND/CT/20/000050 Favipiravir Tablets 200/400/800 mg	M/s Hetero	Firm didn't turn up for presentation.
3.	SND/CT/20/000074 Favipiravir Tablets 200/400/800 mg Active surveillance study post new drug approval.	M/s Mylan	As per the condition of the marketing authorization of Favipiravir Tablets 200/400/800 mg to conduct Phase IV clinical trial, the firm presentenced their Phase IV Clinical trial protocol of Favipiravir. After detailed deliberation committee recommended for grant of Phase IV Clinical trial subject to following conditions: - 1. Sample size to be recalculated with justification. 2. More government site should be included. .
4.	SND/MA/20/000321 Combi Kit of Favipravir 200/800 mg tablet (2 tablets of Favipiravir 200 mg and 30 Tablets of Favipiravir 800 mg)	M/s Mylan	Firm presented the proposal for marketing authorization of Combi Kit of Favipiravir 200 mg (2 tablets) and Favipiravir 800 mg (30 Tablets). Committee opined that the proposed combipack of Favipiravir 200 mg (2 tablets) and Favipiravir 800 mg (30 Tablets) is not justified. Accordingly, after detailed deliberation the committee recommended that the firm may revise the proposal as per approved Combi-pack i.e. Favipiravir 200 mg (2 tablets) and Favipiravir 800 mg (16 Tablets)

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GCT Division			
5.	CT/133/20 Online submission (22966) EDP 1815	M/s Spectra Hospital Service Limited	The firm presented their proposal for Phase II/III Clinical trial protocol before the committee. **Assessment of risk vs. Benefit to the** patients: The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity, Phase-I & II clinical study justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** The Purpose of the study To determine if a specific intervention reduces the composite of progression of patients with COVID-19-related disease to organ failure or death **Unmet Medical need in the country:** The test drug may potentially provide treatment in patients with COVID-19-related disease to organ failure or death After detailed deliberation the committee recommended for grant of permission to conduct the study with subject to the condition that :- 1) Firm should clearly define the uniform standard of care in the proposed Protocol. 2) Firm should include 50% government sites across the India.
New Drug Division			
6.	ND/CT/20/000141 Inosine Pranobex	M/s Themis Medicare Ltd	The firm presented their proposal for Phase III Clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III Clinical Trial in moderate COVID-19 Patients subject to condition that the trial should be a blinded trial and accordingly revised protocol should be submitted to CDSCO for approval.
7.	ND/CT/20/0000063 Inhalation product of Chlorine	M/s Supreme Industries	In light of earlier recommendation dated 02.12.2020, the firm presented their clarification for acute & sub-acute Inhalation toxicity studies in animals & Phase I Clinical Trial Protocol before the committee.

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			Earlier the committee recommended for grant of permission to conduct phase I Clinical Trial subject to clarification from the firm on certain aspects of animal toxicity data. The committee reiterated it's recommendations and decided to provide it's comments on the clarification presented by the firm in a couple of days