Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 210th meeting held on 10.02.2022 at CDSCO (HQ), New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	IND/CT/21/000041 Aqueous Chloride	Supreme Drugs Pvt Ltd (Formerly Supreme Industries)	In light of the earlier recommendation dated 2.07.2021, the firm presented their Phase II clinical trial report and Phase III clinical trial Protocol. After detailed deliberation, the committee recommended that, the firm should revise the protocol for the Phase-III Clinical Trial and the design of the trial should be double blind placebo controlled clinical trial comparing the test drug plus SOC with placebo plus SOC in mild Covid-19 patients subject to the following conditions:- 1. Trial should be conducted at 3 to 4 centres. 2. Principal Investigator should be Medical specialist at each centre. Accordingly revised protocol should be submitted for further review by the committee.
2.	ND/CT/20/000089 Inosine Pranobex 500mg tab.	M/s Themis	In light of earlier recommendations of the SEC dated 28.12.2021, the firm presented their proposal for approval of Inosine Pranobex in emergency situation along with results of completed Phase-II and Phase III clinical trial conducted in the country The clinical trial results show statistically significant earlier clinical improvement in Inosine Pranobex group as compared to the standard of care group. After detailed deliberation, in the light of current pandemic situation due to Covid-19, the committee recommended for grant of permission to manufacture and market Inosine Pranobex tablets 500mg for restricted use under emergency situation in the country as add-on therapy for treatment of mild Covid-19 patients with co-morbidities and moderate Covid-19 patients subject to the following condition:- 1. The product should be sold by retail under the prescription of medical

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			specialists only . 2. The firm should conduct active PMS study for which protocol should be submitted for further review by the committee. 3. The firm should submit the package insert and fact sheet of the product.
SND Division			
3.	SND/MA/20/000219 Glutathione for injection 600 mg	M/s Zuventus Healthcare	The firm didn't turn for presentation.
4.	SND/MA/20/000198 Thymosin α-1 for injection 1.6 mg	M/s Gufic Bios ciences	In light of earlier SEC recommendation held on 10.01.2022, the firm presented the clinical trial data alongwith data in respect of mortality rate in patients on mechanical ventilation with pneumonia and with Covid pneumonia & effect of Thymosin α-1 in patients on mechanical ventilation with Covid infection. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Thymosin α-1 for injection 1.6 mg for restricted use under emergency situation in the country as add-on therapy for the treatment of moderate to severe Covid patients requiring ventilator support (NIV as well as Mechanical ventilation) subject to condition that 1. The product should be sold by retail under the prescription of medical specialists only. 2. The firm should conduct active PMS study for which protocol should be submitted for further review by the committee. 3. The firm should submit the package insert and fact sheet of the product.