Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 237th meeting held on 18.10.2022 at CDSCO, HQ New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/21/000089 Inosine Pranobex Tablets 500 Mg Tablets	M/s Themis Medicare ltd.	The firm presented their proposal ofActive PMS study of Inosine Pranobex 500mg tablets for already approved indications (Covid & Non Covid) along with protocol before the committee. After detailed deliberation, the committee opined that the firm needs to revise the protocol for covid indication study including adequate sample size, RTPCR Tests (should be done before & after the treatment arm). Revised protocol to be submitted to CDSCO for further review by SEC experts.
2.	ND/MA/22/000064 N-C10-16-alkyl trimethylene di-reaction products with chloroacetic acid 1.0000% w/w	M/s Chemkraft Home Care Pvt. Ltd.	The firm presented their proposal for grant of manufacturing and marketing permission of Amines N-C10-16 –alkyl trimethylene di,-reaction products with chloro acetic acid 1.0000%w/w- Multipurpose Disinfectant before the committee. After detailed deliberation, the committee opined that the firm should submit the long term safety data & further the matter should be deliberated before the committee along with dermatologist.
SND Division			
3.	SND/MA/22/000111 Nitric Oxide Nasal Spray	M/s Glenamrk Pharmaceuticals	In light of previous recommendation of SEC (Covid-19) meeting dated 06.05.2022, the firm presented their proposal with additional clinical and in-vitro data in support of proposed additional indication before the committee. After detailed deliberation the committee opined that firm should submit available published literature in public domain and power point presentation made by the firm to CDSCO for further evaluation by the experts.
4.	SND/MA/22/000196 Inosine Pranobex Tablets 1000 Mg	M/s Themis Medicare	The firm presented their proposal of manufacture and marketing permission of Inosine Pranobex 1000mg Tablets with already approved indication for Inosine

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
			Pranobex500mg Tablets as***"Add-on therapy for treatment of mild Covid-19 patients with co-morbidities and moderate Covid-19 patients, Mucocutaneous infections due to herpes simplex virus (type 1 and or type II), genitalwarts as adjunctive therapy topodophyllin or carbon dioxide laser, Subacute sclerosingpanencephalitis, Influenza and other acute respiratory viral infections" with BA/BE study and local CT waiver before the committee.*** After detailed deliberation, the committee recommended for grant of manufacture and marketing permission of Inosine Panobex 1000mg Tablets for already approved indication for Inosine Panobex 500mg Tablets as mentioned above subject to condition that ***"the firm should conduct active PMS study with minimum of 100 subjects and submit study datato CDSCO after marketing the drug product".***