Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 225TH meeting held on 06.05.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/21/000153 Nitric Oxide Nasal Spray	M/s Glenmark Pharmaceuticals Ltd.	The firm presented the proposal of removal of condition of requirement of the prescription of RMP for sale of the product by retail. The committee noted that the product has been approved for treatment of adult high risk patients with mild COVID-19 having risk of progression of the disease. After detailed deliberation, the committee recommended that in light of the approved indication, the firm should submit detailed justification with clinical evidences and supportive data to CDSCO & present the same before the committee for further consideration.
2.	ND/MA/22/000064A mines, N-C10-16 – alkyl trimethylene di,- reaction products with chloro acetic acid 1.0000%w/w	M/sChemkraft Home Care Pvt. Ltd.	The firm presented the proposal of manufacture and market of multipurpose disinfectant before the committee. The committee noted that the proposed product is not approved anywhere in the world and also noted that firm has not submitted the following: 1. Clear intended indication for the proposed product for manufacture and marketing. 2. Microbiological-efficacy data supporting intended use/indication in human as well as surfaces. 3. Data on human/animal/environmental hazard. 4. Toxicological profile/eco-toxicological profile data. 5. Adequate data on human safety with respect to respiratory tract and mucosa. 6. Material safety data sheet. 7. Do's and don'ts, advisory & leaflet for use of the proposed product. 8. Published human safety data. In view of above, the committee recommended that the firm should submit above

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			information/documents and also the firm should submit the proposal for conduct of the efficacy study for the proposed claim to CDSCO for further review by the committee.
SND Division			
3.	SND/CT/21/000097 Favipiravir dry powder inhaler (DPI) 10mg	M/s SAVA Healthcare Limited	The firm has presented the Phase III clinical trial protocol before the committee for approval. After detailed deliberation the committee opined that the data presented was not adequate to support the conduct of Phase III CT . Accordingly, the firm should submit the protocol for conduct of Phase I/II CT study in which Principal investigator should be a pulmonologist along with justification & supportive literature for once a day dose of 10mg / 20mg, for further review by the committee.
4.	SND/IMP/21/000057 Klerwipe WFI 70/30 (IPA-based disinfectant wipes) (Hard surface disinfectant)	M/s ECO Labs	In light of SEC recommendation dated 13/09/2021, the firm presented in-vitro efficacy study data against enveloped viruses. After detailed deliberation the committee recommended for grant of permission to import and market the product, for disinfection of floor, walls and other hard surfaces against various pathogens like bacteria, virus etc including Corona virus.
5.	SND/IMP/21/000063 Klercide Sporicidal Enhanced Peroxide (Hydrogen Peroxide disinfectant liquid)	M/s ECO Labs	In light of SEC recommendation date 13/09/2021, the firm presented in-vitro efficacy study data against enveloped viruses. After detailed deliberation the committee recommended for grant of permission to import and market the product, for disinfection of floor, walls and other hard surfaces against various pathogens like bacteria, virus etc including Corona virus.
6.	SND/MA/22/000111 Nitric Oxide Nasal Spray	M/s Glenmark Pharmaceutical s Ltd.	The firm presented the proposal of additional indication of Nitric Oxide Nasal Spray along with clinical data and regulatory status in other countries. The committee noted that the product has been approved for treatment of adult high risk patients with mild COVID-19 having risk of progression of the disease.

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			After detailed deliberation, the committee opined the data presented was not adequate in light of already approved indication. Accordingly the firm should submit detailed justification with clinical evidences and supportive data to CDSCO & present the same before the committee for further consideration.