

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 207th meeting held on 03.02.2022 at CDSCO (HQ), New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/IMP/21/00038 NONS	M/s. Glenmark Ltd	<p>In light of earlier recommendation of SEC (COVID) dated 13.01.2022, firm presented their proposal for approval of Nitric Oxide Nasal Spray (NONS) in emergency situation along with results of completed Phase-III clinical trial conducted in the country.</p> <p>The firm presented the results as under-</p> <ol style="list-style-type: none"> 1. Statistically Significant reduction in log viral load in NONS group compared to Placebo group (normal saline). 2. Significantly higher proportion of subjects in NONS group achieved RT-PCR negative conversion compared to Placebo 3. NONS demonstrated significant clinical improvement <p>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 Nitric Oxide Nasal Spray (NONS) for restricted use under emergency situation in the country for treatment of adult high risk patients with mild COVID-19 having risk of progression of the disease subject to the following condition-</p> <ul style="list-style-type: none"> • The product should be sold under the prescription of RMP. • The firm should conduct Phase IV trial for which protocol should be submitted for further review by the committee. • Firm shall submit the package insert and fact sheet of the product.
2.	ND/CT/22/000001 Nitric oxide Nasal Spray	M/s. Meril	<p>The firm presented the proposal for Phase III Clinical trial protocol before the committee.</p> <p>After detailed deliberation committee opined that the design of the product is different from that of innovator which may lead to different release profile of</p>

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			<p>Nitric Oxide.</p> <p>Accordingly, firm should submit comparative assessment of their product with innovator product along with the Phase II CT protocol before committee for further consideration.</p>
SND Division			
3.	<p>SND/IMP/21/0000048</p> <p>Klercide –Low residue Quat Metered Dose Concentrate Containing , Didecyl dimethyl ammonium chloride (DDAC) 2.0% (3.6 % w/w) in 100 ml (Hard Surface Disinfectant)</p>	M/s. Eco Labs	<p>In light of SEC recommendation date 13/09/2021. The firm presented in-vitro efficacy study data against enveloped viruses.</p> <p>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 Coronavirus.</p>
4.	<p>SND/IMP/21/0000056</p> <p>Klercide Sporicidal Active Chlorine – based disinfectant liquid , for disinfection of floor, walls and other hard surfaces , specifically effective against COVID – 19 causing Corona Virus (hard surface disinfectant)</p>	M/s. Eco Labs	<p>In light of SEC recommendation date 13/09/2021 the firm presented in-vitro efficacy study data against enveloped viruses.</p> <p>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 Coronavirus.</p>