

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 201<sup>st</sup> meeting held on 10-01-2022 at CDSCO, HQ New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
<b>New Drug Division</b>			
1.	<b>IND/CT/21/000041</b> Life Viro Treat 10 mL vial (Chlorine 1 mg/m <sup>3</sup> )	M/s Supreme Drugs Pvt. Ltd.	<p>The firm presented the Phase II Clinical trial report along with the request of Emergency Use Authorisation before the committee.</p> <p>After detailed deliberation the committee noted the following:</p> <ol style="list-style-type: none"> <li>1. The data presented by the firm is not adequate for considering approval of the product for restricted use under the emergency situation for the product.</li> <li>2. The firm should reanalyse the result including the safety data, causality assessment of death etc. and present the same before the committee.</li> <li>3. If, the result of the study is found satisfactory, the firm will be required to conduct the Phase III Clinical trial with robust study design including assessment of clinical endpoints and accordingly, plan / protocol to be submitted to CDSCO.</li> </ol>
<b>SND Division</b>			
2.	<b>SND/IMP/21/0000048</b> Klercide - Low Residue Quat Metered Dose Concentrate containing, Didecyl dimethylammonium chloride (DDAC) 2.0 % (3.6 % w/w) in 100 ml (Hard surface disinfectant)	M/s Eco Labs	The firm did not turn up.
3.	<b>SND/IMP/21/0000056a</b> Klercide Sporidical Active Chlorine (0.5%), Chlorine-based disinfectant liquid, For disinfection of floor, walls and other hard surfaces, specifically effective against COVID-19 causing Coronavirus (Hard surface disinfectant)	M/s Eco Labs	The firm did not turn up.

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4.	SND/MA/20/000198 Thymosin $\alpha$ -1 for injection 1.6 mg	M/s Gufic Biosciences	In light of earlier SEC recommendations held on 12.10.2021, the firm presented the data in respect of time to clinical improvement for both the group along with comparison of their results with the results published in literature on Thymosin alpha-1 for injection 1.6mg. After detailed deliberation the Committee opined that firm should present following data:- 1. Mortality rate in a patients on mechanical ventilation with pneumonia and with Covid pneumonia. 2. Effect of Thymosin $\alpha$ -1 in patient on mechanical ventilation with Covid infection.