

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 214<sup>th</sup> meeting held on 28.02.2022 at CDSCO (HQ), New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
<b>New Drug Division</b>			
1.	IND/CT/21/000041 Aqueous Chloride	M/s. Supreme Drugs Pvt Ltd (Formerly Supreme Industries)	<p>In the light of earlier SEC recommendation dated 10.02.2022, the firm presented Phase II clinical trial report along with the Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial on submission of details of each clinical trial sites along with undertaking by the investigators to CDSCO.</p>
<b>SND Division</b>			
2.	SND/MA/20/000219 Glutathione for injection 600 mg	M/s. Zuventus Healthcare	<p>The firm presented its proposal for grant of additional indication with the results of clinical trial of Glutathione for injection 600 mg <b>as an add-on to the standard of care in moderate COVID-19 patients suffering from respiratory distress.</b></p> <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 Glutathione for injection 600 mg for restricted use under emergency situation in the country for additional indication i.e <b>“As an add-on to the standard of care in moderate COVID-19 patients.”</b> subject to the following conditions:-</p> <ol style="list-style-type: none"> <li>1. The product should be sold by retail under the prescription of medical specialists only .</li> <li>2. The firm should submit the package insert and fact sheet of the product.</li> </ol>