

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 202<sup>nd</sup> meeting held on 13-01-2022 at CDSCO, HQ New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
<b>New Drug Division</b>			
1.	NONS	M/s Glenmark	<p>In light of the earlier recommendations, the firm presented the reanalysed data in high risk patients.</p> <p>The committee observed that the clinical trial is not completed and the data presented was interim &amp; inadequate as the sample size of high risk patients was small.</p> <p>After detailed deliberation, the committee recommended that the firm may submit the data from clinical trials ongoing in other countries and may amend the protocol to include the high risk patients with comorbidity including elderly patients suitable for the claim.</p> <p>Accordingly, the firm should submit the amended protocol and the data for further review by the committee.</p>