Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 189th meeting held on 12.10.2021 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	The firm presented their proposal for amendment in the Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of approval for protocol amendment.
2.	ND/IMP/21/000038 NONS	M/s Glenmark Ltd	The firm presented their proposal for manufacturing and marketing of Nitric Oxide Nasal Spray in India along with the comparability of their product with imported Nitric oxide Nasal spray manufactured by M/s Sanotize. After detailed deliberation, the committee recommended that firm should submit the complete clinical trial report of the ongoing Phase III clinical trial of the imported nitric oxide nasal spray for further consideration.
SND Division			
3.	SND/IMP/21/000090 Baricitinib Tablets 2mg & 4mg	M/s Ely Lilly	The firm presented the proposal for expansion of indication along with the clinical study data. The committee noted that the USFDA has broadened the Emergency Use Authorisation (EUA) for Baricitinib to allow Baricitinib for treatment with or without Remdesivir in COVID-19. After detailed deliberation, the committee recommended for grant of permission for the indication, "Baricitinib for treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO).
4.	SND/MA/20/000198 Thymosin α-1 for injection 1.6 mg	M/s Gufic Biosciences	In light of earlier SEC recommendations held on 02.07.2021, the firm presented Clinical trial report. After detailed deliberation, the committee opined that the firm should analyse & present the data in respect of time to clinical

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			improvement for both the groups along with comparison of their results with the results published in literature on Thymosin alpha-1 for Injection 1.6mg to consider the matter further.