

Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 233th meeting held on 02.08.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/22/000038 Ramatroban 75 mg Tablet Protocol no. RAMBAN-1, Vr 01	M/s. JSS Medical Research	The firm presented their proposal for grant of permission to conduct Phase II/III clinical trial with drug Ramatroban 75 mg tablet. After detailed deliberation, the committee recommended for grant of permission to conduct Phase II/III clinical trial with drug Ramatroban 75 mg tablet as per protocol presented.
SND Division			
2.	SND/IMP/22/000153 Liquid nasal spray (Nitric Oxide)(100 PPM)	M/s. Meril Diagnostics	The firm presented their proposal for grant of manufacture and marketing permission of Liquid Nasal Spray (Nitric Oxide) (100ppm) for already approved indication along with release procedure and In-vitro study data of the applied drug product before the committee. After detailed deliberation, the committee opined that the firm needs to show clinical efficacy of the applied drug product in COVID positive patient with data of clearance of virus load from nasal cavity, as RTPCR negative test after 3 rd , 4 th and 5 th day of patient tested COVID positive etc., with sample size between 30-36 in a single arm study. Accordingly, firm should submit Clinical Study Protocol for further review by the committee.
GCT Division			
3.	CT/161/21 AZD 1222	M/s. IQVIA	In light of earlier SEC recommendation dated 13.05.2022, the applicant has presented protocol amendment 1, IND-1 dated 31-03-2022 along with justification for sample size calculation. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed phase II study.