

Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 241th meeting held on 20.01.2023 at CDSCO (HQ), New Delhi:

Age nda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	IND/MA/22/000064N -C10-16 alky; trimethylene Di- reaction products with chloro acetic acid 1.0000 % w/w Multipurpose Disinfectant	M/s Chemkraft Home care Pvt. Ltd.	<p>The firm presented their proposal for grant of Manufacturing & Marketing permission of Amines, N –C10-16-alkyl trimethylene di,-reaction products with chloro acetic acid 1.0000% w/w (Kraftshield-Multipurpose Disinfectant) before the committee with respect to long term safety data which is reviewed by the committee.</p> <p>After detailed deliberation the committee recommended for grant of permission to manufacture and market of Amines, N–C10-16-alkyl trimethylene di,-reaction products with chloro acetic acid 1.0000% w/w (Not for Covid use).</p> <p>The firm should submit the Adverse Event (AE) report (if any) reported due to use of this product as part of PMS.</p>
SND Division			
2.	SND/MA/22/0000111 Nitric Oxide Nasal Spray	M/s Glenmark Pharmaceuticals	<p>In light of previous recommendation of SEC (Covid-19) meeting dated 16.11.2022, the firm presented their proposal before the committee.</p> <p>After detailed deliberation the committee opined that, the firm did not present strong evidence on the use of applied drug product for prevention of COVID-19 infection.</p> <p>In view above, the committee did not recommend for approval of the proposal of additional indication of Nitric Oxide Nasal Spray due to lack of strong evidence for proposed indication.</p>
3.	SND/MA/22/0000153 Liquid Nasal Spray (Nitric Oxide)	M/s Meril Diagnostic	<p>In light of previous recommendation of SEC (Covid-19) meeting dated 02.08.2022, the firm presented their proposal alongwith single arm Clinical Study protocol before the committee.</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the</p>

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			proposed single–arm Clinical study as per protocol presented.