

**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 182<sup>rd</sup> meeting held on 13.09.2021 at CDSCO, HQ New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
<b>SND Division</b>			
1.	<p>SND/IMP/21/0000048</p> <p>Low Residue Quat Metered Dose concentrate containing, Didecyl Dimethyl ammonium chloride (DDAC) 2.0% (3.6% w/w) in 100 ml (Hard surface disinfectant)</p>	M/s ECO Labs	<p>The firm presented the proposal along with supportive documents for import and market of the product with the claim - for disinfection of floors, walls and other surfaces, specifically effective against Covid-19 causing Corona virus.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the supporting documents including, in-vitro efficacy study data along with the detailed methodology adopted for assessment of efficacy against Corona virus and copy of the regulatory approvals from countries where the product is marketed mentioning the details of approval for corona virus.</p>
2.	<p>SND/IMP/21/000056</p> <p>Klericide Sporicidal Active chloride (0.5%), chloride-Based disinfectant of Floor, wall and other hard surfaces, specifically effective against COVID-19 capsule Coronavirus (Hard surface disinfectant)</p>	M/s ECO Labs	<p>The firm presented the proposal along with supportive documents for import and market of the product with the claim - for disinfection of floors, walls and other surfaces, specifically effective against Covid-19 causing Corona virus.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the supporting documents including, in-vitro efficacy study data along with the detailed methodology adopted for assessment of efficacy against Corona virus and copy of the regulatory approvals from countries where the product is marketed mentioning the details of approval for corona virus.</p>
3.	<p>SND/IMP/21/000057</p> <p>Klerwipe WFI 70/30 (IPA-based disinfectant wipes) (Hard surface disinfectant)</p>	M/s ECO Labs	<p>The firm presented the proposal along with supportive documents for import and market of the product with the claim - for disinfection of floors, walls and other surfaces, specifically effective against Covid-19 causing Corona virus.</p> <p>After detailed deliberation, the committee recommended that the firm should submit</p>

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4.	<p>SND/IMP/21/000058</p> <p>Klercide Sporicidal Active Chlorine Unit Dose Concentrate (Chlorine-based disinfectant concentrate)</p>	M/s ECO Labs	<p>The firm presented the proposal along with supportive documents for import and market of the product with the claim - for disinfection of floors, walls and other surfaces, specifically effective against Covid-19 causing Corona virus.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the supporting documents including, in-vitro efficacy study data along with the detailed methodology adopted for assessment of efficacy against Corona virus and copy of the regulatory approvals from countries where the product is marketed mentioning the details of approval for corona virus.</p>
5.	<p>SND/IMP/21/000062</p> <p>Klercide Low Residue Quat (Quaternary Ammonium – based disinfectant liquid)</p>	M/s ECO Labs	<p>The firm presented the proposal along with supportive documents for import and market of the product with the claim - for disinfection of floors, walls and other surfaces, specifically effective against Covid-19 causing Corona virus.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the supporting documents including, in-vitro efficacy study data along with the detailed methodology adopted for assessment of efficacy against Corona virus and copy of the regulatory approvals from countries where the product is marketed mentioning the details of approval for corona virus.</p>
6.	<p>SND/IMP/21/000063</p> <p>Klercide Sporicidal Enhanced Peroxide (Hydrogen Peroxide disinfectant liquid)</p>	M/s ECO Labs	The firm presented the proposal along with supportive documents for import and market of the product with the claim - for disinfection of floors, walls and other surfaces, specifically effective against

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			<p>Covid-19 causing Corona virus.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the supporting documents including, in-vitro efficacy study data along with the detailed methodology adopted for assessment of efficacy against Corona virus and copy of the regulatory approvals from countries where the product is marketed mentioning the details of approval for corona virus.</p>
7.	<p>SND/IMP/21/000064</p> <p>Klerwipe Low Residue Peroxide Wipes (Hydrogen Peroxide based disinfectant wipes)</p>	M/s ECO Labs	<p>The firm presented the proposal along with supportive documents for import and market of the product with the claim - for disinfection of floors, walls and other surfaces, specifically effective against Covid-19 causing Corona virus.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the supporting documents including, in-vitro efficacy study data along with the detailed methodology adopted for assessment of efficacy against Corona virus and copy of the regulatory approvals from countries where the product is marketed mentioning the details of approval for corona virus.</p>
<b>New Drug Division</b>			
8.	<p>ND/IMP/21/000038</p> <p>Nitric Oxide Nasal Spray for COVID-19</p>	M/s Glenmark Ltd.	<p>The firm presented the proposal for amendment in the Phase III protocol from Version 3.0 dt 05.08.2021 to Version 4.0 dt. 07.09.2021.</p> <p>After detailed deliberation, the committee recommended for the grant of approval for the proposed amendment.</p>