**Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 199th meeting held on 28.12.2021 at CDSCO, HQ New Delhi:**

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendation |
|---|---|---|---|
| **New Drug Division** | | | |
| 1. | ND/CT/20/000089<br><br>Inosine Pranobex 500mg | M/s Themis Ltd. | The firm presented the results of Phase III clinical trial along with the published data before the committee. The committee noted that there is no difference in terms of Clinical Improvement at day 11 between the Inosine Pranobex group and Standard of Care group, although there are some Clinical Improvement in the Inosine Pranobex group observed at day 6.<br><br>Further, the clinical data from the other countries presented were mostly retrospective analysis and were not convincing as such data are also not based on robust scientific design required for clinical study.<br><br>In view of above, the committee after detailed deliberation recommended that further clinical data is required to assess the efficacy of Inosine Pranobex in mild to moderate Covid-19 patients with risk factor like hypertension, diabetes, cardiovascular disorders, etc to assess the potential efficacy of the drug in clinical improvement including reduction of disease progression, hospitalization and death for further consideration.<br><br>Accordingly, the firm may submit their plan/ proposal for further consideration by the committee. |
| 2. | ND/IMP/21/000038<br>NONS | M/S Glenmark | The firm presented the interim Phase III clinical trial results of NONS before the committee.<br>The Committee observed that the clinical trial results indicates significant reduction in viral load in the treatment group as compared to the SOC group. However, to consider the request of the firm for approval of the drug for treatment of mild to moderate Covid-19 patients, more clinical trial data especially in terms of efficacy of the product in mild patients with high risk of disease progression, is required.<br><br>In view of above, the committee after detailed |

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| | | | deliberation recommended that the firm may generate the additional efficacy data in patients who are at high risk of progression of disease through appropriate amendment of the protocol of the ongoing trial and also analysing the data of high risk patients already included in the study. Accordingly, the firm may submit their proposal for further consideration by the committee. |
| **SND Division** | | | |
| 3. | SND/IMP/21/000048 Klercide - Low Residue Quat Metered Dose Concentrate containing, Didecyldimethylammonium chloride (DDAC) 2.0 % (3.6 % w/w) in 100 ml (Hard surface disinfectant) | M/s Eco Labs | The firm did not turn up for presentation |
| 4. | SND/IMP/21/000056 Klercide Sporicidal Active Chlorine (0.5%), Chlorine-based disinfectant liquid, For disinfection of floor, walls and other hard surfaces, specifically effective against COVID-19 causing Coronavirus (Hard surface disinfectant) | M/s Eco Labs | The firm did not turn up for presentation |
| 5. | SND/CT/21/000093<br><br>Favipiravir Tablet 400 mg | M/s Sun Pharma | The firm presented the Phase IV clinical trial protocol before the committee.<br>After detailed deliberation, the committee recommended for grant of permission to conduct the study . |