**Recommendations of the SEC (Antimicrobial & Antiviral) made in its 126th meeting held on 31.05.2023 at CDSCO HQ New Delhi:**

| S.No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **SND Division** | | | |
| 1. | 12-52/2023-DC (Pt- Misc/SND)<br><br>Liposomal Amphotericin B for Injection 50 mg | M/s. Gilead | The firm presented the proposal for the grant of permission to conduct a non-interventional post-marketing study in India, before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission for conduct of active PMS for liposomal Amphotericin B Injection 50 mg. |
| 2. | SND/MA/23/000123 Clarithromycin ER tablets 1000mg | M/s. Abbott Healthcare Pvt. Ltd. | The firm presented the proposal for grant of permission to manufacture and marketing of Clarithromycin ER Tablets 1000mg, along with the report for local clinical trial waiver before the committee.<br>The committee observed that the justification presented by the firm is inadequate.<br><br>After detailed deliberation, the committee did not consider for clinical trial waiver and recommended that, the firm should conduct BE study along with Phase III clinical trial.<br>Accordingly, firm should submit Phase III CT protocol for further review by the committee. |
| **FDC Division** | | | |
| 3. | FDC/MA/23/000054<br><br>Methylcobalamin 1500mcg + Alpha Lipoic acid 100mg + Vitamin D3 IP 8000IU + Calcium Carbonate IP eq. to elemental Calcium 225mg + VitaminK2-7 50mcg + Zinc Sulphate USP eq. to elemental Zinc 7.5mg + Magnesium Oxide IP eq. to elemental Magnesium 50mg capsules | M/s. Quality Pharma Products Pvt. Ltd. | The firm presented the proposal before the committee along with the justification for BE/ clinical trial waiver.<br><br>After detailed deliberation, the committee considered the request of firm for BE/ clinical trial waiver and recommended for grant of permission to manufacture and market the proposed FDC subject to the condition that the firm should conduct active PMS study in the country with adequate number of subjects for which protocol should be submitted to CDSCO within three months from the date of approval for review by SEC. |

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|---|---|---|---|
| 4. | FDC/MA/22/000405<br><br>Rifapentine 150mg + Isoniazid 150mg tablets | M/s. J Duncan Healthcare Pvt. Ltd. | The firm did not turn up for presentation. |
| 5. | FDC/MA/23/000106<br><br>Calcium Aspartate 1120mg + Magnesium Hydroxide 180mg + Vitamin D3 IP 1000 IU tablets | M/s. Oversease | The firm presented the proposal before the committee along with the justification for BE/clinical trial waiver.<br><br>After detailed deliberation, the committee considered the request of firm for BE/ clinical trial waiver and recommended for grant of permission to manufacture and market the proposed FDC subject to the condition that the firm should conduct active PMS study in the country with adequate number of subjects for which protocol should be submitted to CDSCO within three months from the date of approval for review by SEC. |
| 6. | FDC/MA/23/000128<br><br>Ascorbic Acid IP 50mg + Cholecalciferol (Vitamin D3) IP 200IU + D-Panthenol IP 2.5mg + Nicotinamide IP 15mg + Pyridoxine Hydrochloride IP 1mg + Riboflavin Sodium Phosphate IP eq. to Riboflavin 1mg + Thiamine Hydrochloride IP 2mg + Vitamin A (as palmitate) IP 2500IU + Cyanocobalamin IP 1mcg + Citrus Bioflavonoid Compound 5mcg syrup | M/s. Hindustan Laboratories | The firm presented the proposal before the committee along with the justification for BE/ clinical trial waiver.<br><br>After detailed deliberation, the committee considered the request of firm for BE/ clinical trial waiver and recommended for grant of permission to manufacture and market the proposed FDC subject to the condition that the firm should conduct active PMS study in the country with adequate number of subjects for which protocol should be submitted to CDSCO within three months from the date of approval for review by SEC. |