Recommendations of the SEC (Dentistry) made in its 08th meeting held on 31.05.2023 & 16.06.2023 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/000508 Metronidazole Extended Release Tablet 600 mg	M/s. Abbott Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated 18.12.2022, the firm presented the PK data in support of their proposal for additional indication of Metronidazole extended release tablet 600mg. After detailed deliberation, the committee recommended that the firm should present data to support safety of proposed dose of Metronidazole extended release tablets 600mg (proposed dose: 2 tablets x 600mg OD) for 5 days. Further, the firm needs to submit complete comparative PK data along with blood-level data profile (C_{max}, T_{max}, AUC_{0-T} and $AUC_{0-\infty}$) of Metronidazole extended release tablets 600mg (proposed dose: 2 tablets x 600mg OD) with Metronidazole conventional tablets 400mg (TID) for further review by the committee.
FDC Division			
2.	FDC/MA/19/000115 Streptococcus salivarius UBSS-01 1.0 Billion cfu + Lactobacillus salivarius UBLS-22 0.5 Billion cfu + Lactobacillus acidophilus UBLA-34 0.5 Billion cfu+ Lactobacillus rhamnosus UBLR-58 0.5 Billion cfu + Lactobacillus paracasei UBLPc-35 0.5 Billion cfu + Lactobacillus plantarum UBLP-40 0.5 Billion cfu+	M/s. Unique Biotech Ltd.	In light of the earlier SEC recommendation dated 14.09.2021, the firm presented the proposal before the committee along with Phase III clinical trial protocol. The firm informed the committee that the product is not approved anywhere in the world for the proposed indication. After detailed deliberation, the committee recommended that the firm should revise the protocol including the following: 1. The study design w.r.t blinding, randomization, inclusion criteria, treatment, dispensing of formulation should be revised. 2. Method adopted for Statistical analysis.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Lactobacillus reuteri UBLRu-87 0.2 Billion cfu EnkorInstamelt Sachet		3. Details of antibiotics to be used in the study. 4. The investigators should be the experts of the disease for which trial is proposed to be conducted. The committee also recommended that firm should present the following points before presenting the revised CT protocol: 1. Rationality for the proposed FDC. 2. Justification for combination of various probiotics and dose regime. 3. Mechanism of action of the formulation and route of administration. 4. Bioavailability of the drug. 5. Details of measures to be taken for ensuring proper storage conditions in the supply chain for supplying drug to study sites as probiotics are temperature sensitive. The committee also recommended that the firm should submit the justification along with revised Phase III clinical trial protocol to CDSCO for review by the committee.
Medical Device Division			
3.	CI/MD/2023/58243 Dental Implant with Nanotubular surfaces (Brand Name: NMITLI Nanosurface Dental Implant)	Maulana Azad Institute of Dental Sciences	The institute presented proposal for pilot clinical investigation of the proposed product Dental Implant with Nanotubular surfaces (Brand Name: NMITLI Nanosurface Dental Implant) in the country on Indian population before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of pilot clinical investigation of the proposed product in the country on Indian population. Further, details of co-investigator needs to be included in the clinical investigation protocol.