Recommendations of the SEC (Analgesic & Rheumatology) made in its 96th meeting held on 16.05.2023 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2023/ 36412 Teriparatide Solution for injection 600mcg/2.4mL in Pre filled disposable pen	M/s. Intas Pharmaceuticals Ltd.	The firm presented the proposal for conduct of Phase IV clinical trial of Teriparatide solution for injection 600mcg/2.4ml in prefilled disposable pen titled "A prospective, single arm, multicentre study to assess the immunogenicity potential of Teripartaide manufactured by Intas Pharmaceuticals Limited in postmenopausal women with Osteoporosis" vide protocol No. 0110-21, Version No. 1.1 Dated 19 November 2022. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-IV clinical trials subject to the condition that the firm should revise the protocol as under- "In the exclusion criteria, history of drug "Leflunomide" taken should be revised to 2 years instead of 6 months prior to screening". Accordingly, the firm should submit the revised protocol to CDSCO.
SND Division			
2.	SND/CT/23/000001 Nimesulide Granules for Suspension	M/s. Dr. Reddy's Lab Ltd.	The firm didn`t turn up for presentation.
FDC Division			
3.	FDC/MA/21/000176 Acetaminophen 325mg+ Tramadol Hydrochloride 37.50mg effervescent tablet	M/s. SciTech Specialities Pvt. Ltd.	In light of the earlier SEC recommendations dated 16.11.2021, the firm presented the BE study report before the committee. The committee noted the BE study report. After detailed deliberation, the committee recommended that the firm should submit the Phase III clinical trial protocol to CDSCO in line of earlier SEC recommendation dated 28.11.2018.
Medical Device Division			
4.	CI/MD/2022/75448 3-D scaffold matrix	M/s. EffecMed Private Limited	The firm presented the proposal for amendment in approved pivotal clinical investigation protocol (EFFECMED/SCAFFOLD/ORTHO/001-

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			2022) of product 3-D scaffold matrix from version 1.0 dated 01.10.2022 to version 2.0 dated 15.03.2023 such as change in reference product, change in clinical investigation site, minor changes in inclusion & exclusion criteria before the committee. After detailed deliberation the committee recommended for grant of permission for conduct of the pivotal clinical investigation of the proposed product 3-D scaffold matrix as per the amended pivotal clinical investigation protocol.
5.	CI/MD/2022/76970 3-D scaffold matrix	M/s. EffecMed Private Limited	The firm presented the proposal for amendment in approved pivotal clinical investigation protocol (EffecMed/Scaffold/Dentistry/001-2022) of product 3-D scaffold matrix from version 1.0 dated 01.11.2022 to version 1.1 dated 01.04.2023 such as change in clinical investigation site, minor changes in inclusion & exclusion criteria before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the pivotal clinical investigation of proposed product 3-D scaffold matrix as per the amended pivotal clinical investigation protocol.
6.	CI/MD/2023/84086 Bone void filler (Serioss)	M/s. Serigen Mediproducts Pvt. Ltd	The firm presented the proposal for pivotal clinical Investigation of the proposed product Bone Void Filler (Serioss) in the country on Indian population before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the pivotal clinical investigation of the proposed product Bone Void Filler (Serioss) in the country on Indian population. The firm should submit the report of clinical investigation to CDSCO for further review.