Recommendations of the SEC (Analgesic & Rheumatology) made in its 82th meeting held on 31.03.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000010 Teriperatide Injection, solution for injection in a pre-filled pen 600mcg/2.4ml (Synthetic Origin)	M/s. Sun Pharmaceutical Industrial Ltd	The firm didn't turn up for presentation.
2.	SND/MA/22/0000 80 Tofacitinib ER Tablets 11mg	M/s Optimus Pharma	The firm presented their proposal for manufacturing and marketing of Tofacitinib extended release tablets 11mg along with BE Study protocol. After detailed deliberation, the committee recommended for the grant of permission to conduct the BE Study as per the protocol presented subject to condition that patients with TB should be excluded from the study.
3.	SND/MA/21/000532 Solubilized taste masked Paracetamol Oral Liquid 125 mg/5ml	M/s Pulse Pharmaceuticals	The firm presented their proposal for manufacturing and marketing of claimed solubilized taste masked Paracetamol Oral Liquid 125 mg/5ml. After detailed deliberation, the committee opined that the firm should conduct BE study comparing with the available conventional dosage forms. Further, the firm should revise the generic name of the product as per the regulatory requirements. Accordingly, the firm should submit BE study protocol for review by the committee.
4.	SND/MA/21/0005 33 Solubilized Taste Masked Paracetamol Oral Liquid 250 mg/5ml	M/s Pulse Pharmaceuticals	The firm presented their proposal for manufacturing and marketing of claimed solubilized taste masked Paracetamol Oral Liquid 125 mg/5ml. After detailed deliberation, the committee opined that the firm should conduct BE study comparing

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			with the available conventional dosage forms. Further, the firm should revise the generic name of the product as per the regulatory requirements. Accordingly, the firm should submit BE study protocol for review by the committee.
GCT Division			
5.	CT/67/21OnlineSubmission (14098) Secukimunab	M/s. Novartis	The proposal was deferred for next meeting to deliberate in presence of rheumatologist.
Medical Device Division			
6.	IMP/MD/2021/33324 Tissue Supplement Collagen	M/s. Tri Cell Biologics Pvt Ltd.	In light of earlier SEC recommendations dated 24.06.2021 & 25.06.2021, the firm presented their proposal for grant of permission to import and market the proposed product before the committee. After detailed deliberation, committee recommended that the firm should submit following: 1. More published clinical data in peer reviewed high impact journals. 2. Since the product is claimed to be marketed for last 6 years in Europe, hence post market surveillance data for large number of patients from Europe need to be submitted to establish safety and efficacy of the product, for further review by the committee.
7.	MFG/MD/2021/37336 Radiopaquegelified Ethanol	M/s Elevate Scientific Private ltd.	In light of earlier SEC recommendations dated 12.01.2022 & 13.01.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of manufacturing license to manufacture the proposed product only for export purpose. If the firm intends to market the proposed product in India, then the firm should submit the pivotal clinical investigation (Phase III) protocol & PMS data of the proposed product from exporting

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			countries to this office for further SEC review.