Recommendations of the SEC (Gastroenterology & Hepatology) made in its 45th meeting held on 17.02.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/21/000149 Sodium alginate IP 1000mg + Potassium Hydrogen Carbonate PhEur 200mg Oral Suspension	M/s. Naxpar Pharma Pvt. Ltd	The firm presented their active post marketing surveillance (PMS) study protocol before the committee. After detailed deliberation, the committee opined that the firm should include the following in the proposed PMS protocol:- 1.Patients with hypertension, renal and cardiac failure, oedema states and hypercalcemic states are to be excluded. However, diagnostic tests should be included in the protocol for exclusion of these patients. 2.Sample size should be recalculated based on treatment emergent adverse events. 3. More clinical trial sites to be included. Further during the deliberation, it was observed that the firm had made many changes in protocol which was not submitted to CDSCO. In view of above, the committee recommended that the firm should submit revised PMS protocol incorporating the above changes as well as other changes made in the protocol to CDSCO for further deliberation before the committee.
GCT Division			
2.	CT/90/19 Online Submission (12401) Topifexor (LJN452) &licogliflozin (LIK066)	M/s. Novartis	In light of earlier recommendation of SEC dated 17.06.2021 & 21.10.2021, the firm presented the proposed Phase IIb protocol CLJN452D12201C amendment Version 01 dated 18.09.2020 (ELIVATE) with rationale and study data before the committee. After detailed deliberation, the committee noted that in the TANDEM study the efficacy objective was not met and there was frequent pruritus and increase in LDL-C and decrease in HDL-C observed in the tropifexor monotherapy and combination therapy group. In the FLIGHT-FXR study, the primary

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			objective was not found met and there was increased TEAE leading to dose reduction or discontinuation. In view of above, the committee reiterated its earlier recommendation dated 17.06.2021and opined that the firm should submit justification for not amending the protocol with respect to primary objective i.e. not comparing the monotherapy with the combination therapy.
3.	CT/01/22 Online Submission (29865) Nitazoxanide Tablets 500mg	M/s. Raptim Research	In light of earlier recommendation dated 19.01.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended for approval of the proposed study.