Recommendations of the SEC (Gastroenterology & Hepatology) made in its 48th meeting held on 17.05.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000129 Tofacitinib Sustained Release Tablets 22 mg	M/s. Mascot Health Series Pvt. Ltd	The firm presented their proposal for manufacturing & marketing of Tofacitinib Sustained Release Tablets 22 mg indicated for the treatment of adult patients with moderate to severe active ulcerative colitis (UC) who have an inadequate response or intolerance to one or more TNF blockers, along with BE study protocol with request for clinical trial waiver. After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study subject to condition that the subjects with BMI between 18.50 to 25kg/m^2 should be included in the study. Further, the committee opined that requirement of conduct of clinical trial should be decided based on outcome of the BE study.
2.	SND/MA/21/000468 Pantoprazole Powder for Oral Suspension 40mg (Sodium Bicarbonate as Buffer)	M/s Alkem Laboratories Ltd	The firm presented the proposal along with results of BE study. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Pantoprazole Powder for Oral Suspension 40mg (Sodium Bicarbonate as Buffer) for the already approved indications.
FDC Division			
3.	FDC/IMP/19/000001 Sodium alginate + sodium Bicarbonate + calcium Carbonate (250 mg/250 mg + 106.500 mg/106.500mg + 162.500 mg/187.500 mg) tablets, suspension	M/s. Reckitt Benckiser (India) Pvt. Ltd.	In light of earlier SEC recommendation dated 19.01.2022, the firm presented the revised active PMS study protocol. After detailed deliberation, the committee recommended for conducting the proposed PMS study. The results of the PMS study should be presented before the committee for review.
Medical Device Division			
4.	CI/MD/2021/45153 Transcutaneous Implant Evacuation	M/s. IR Innovate Research Pvt. Ltd.	The firm presented their proposal for amendment in clinical investigation protocol before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	system		After detailed deliberation, the committee recommended for approval of the amended protocol for conduct of clinical investigation as presented by the firm.