

Recommendations of the SEC (Gastroenterology &Hepatology) made in its 44th meeting held on 19.01.2022 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/000523 Rifaximin Tablets 550mg	M/s. Lupin Limited	<p>The firm presented their proposal for manufacturing and marketing of Rifaximin Tablets 550mg (additional indication) for Irritable Bowel Syndrome (IBS) with diarrhea.</p> <p>After detailed deliberation, the committee recommended for conduct of a Phase III clinical trial of Rifaximin Tablets 550mg for Irritable Bowel Syndrome with diarrhea.</p> <p>Accordingly, the firm should submit Phase III clinical trial protocol for review by the committee.</p>
FDC Division			
2.	FDC/IMP/19/000001 Sodium alginate + Sodium bicarbonate + Calcium Carbonate (250mg/250mg + 106.500mg/106.500m g + 162.500mg/187.500 mg) tabets, per 5ml suspension	M/s. Reckitt Benckiser (India) Pvt. Ltd.	<p>In light of earlier recommendation of SEC dated 20.07.2021, the firm presented Active Post Marketing Surveillance (PMS) Study protocol before the committee.</p> <p>After detailed deliberation, the committee opined that -</p> <ol style="list-style-type: none"> 1. Adequate government sites to be included 2.The patients with hypertension, renal and cardiac failure, oedema states and hypercalcemic states should be excluded. Diagnostic tests should be included in the protocol for exclusion of these patients. <p>In view of above, the committee recommended that the firm should submit the revised protocol for further deliberation by the committee.</p>
3.	FDC/MA/21/000281 Lactobacillus acidophilus LA 5 &Bifidobacterium BB12 1Billion /1gm Sachet	M/s. East India Pharmaceuticals Works Ltd.	<p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee noted that the firm did not present any published literature/ clinical study in support of the proposed indications.</p> <p>Hence, the committee recommended that the firm should make a detailed presentation w.r.t their claims in the next</p>

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GCT Division			
4.	CT/158/21 Online Submission (29308) Mirikizumab	M/s. Eli Lilly	The firm presented Phase III clinical trial proposal before the committee. Assessment of risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical toxicology, Phase I & II studies including repeat dose toxicity study justify the conduct of the trial. Innovation vis-à-vis Existing Therapeutic option: To assess the effect of mirikizumab in the maintenance of endoscopic response in participants from AMAM who completed treatment on blinded SC mirikizumab and achieved endoscopic response at Week 52 of AMAM Unmet Medical need in the country: The test drug may potentially provide treatment in Patients with Crohn's Disease After detailed deliberation, the committee recommended for grant of permission to conduct the study.
5.	CT/01/22 Online Submission (29865) Nitazoxanide Tablets 500mg	M/s. Raptim Research Pvt.Ltd	The firm presented Bioequivalence study with clinical endpoint proposal before the committee. After detailed deliberation, the committee opined that the firm should comply with the following points: 1) The firm should include negative test for parasite in secondary endpoints. 2) The firm should submit bioequivalence study data in healthy volunteers. Accordingly, the firm should modify the protocol and submit the bioequivalence study data for further review by the committee.
BA/BE Division			
6.	12-09/2021/BA-BE/Misc-24/DC (Application No. BABE/CT05/FF/2021/25420) AV104 (Nalmefene) Buccal film 2 mg	M/s. CBCC Global Research LLP	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the inclusion criteria is quite heterogeneous. Therefore, the firm needs to have homogeneity in the

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			inclusion criteria and include patients with cholestatic disease with pruritis only for conduct of the study. Hence, the firm needs to submit revised study protocol for consideration by the committee