Recommendations of the SEC (Gastroenterology & Hepatology) made in its 40th meeting held on 16.09.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT21/FF/2021/26648 Sporlac 500 MCC tablets	M/s SanzymePvt. Ltd.	The firm presented their proposal for manufacturing and marketing of Sporlac500 MCC tablets along with their justification for waiver of local clinical trial before the committee. After detailed deliberation, the committee opined that the firm should submit published literature, adequate safety & efficacy data from other countries for the proposed FDC, advantage & disadvantage of the proposed FDC over the available drugs for the proposed indication, regulatory status in other countries and justification of Clinical Trial waiver as per the provisions of New Drugs and Clinical Trials Rules, 2019 to CDSCO for further review by the committee.
2.	ND/CT21/FF/2021/26938 Sporlac 300 MCC tablets	M/s SanzymePvt. Ltd	The firm presented their proposal for manufacturing and marketing of Sporlac 300 MCC tablets along with their justification for waiver of local clinical trial before the committee. After detailed deliberation, the committee opined that the firm should submit published literature, adequate safety & efficacy data from other countries for the proposed FDC, advantage & disadvantage of the proposed FDC over the available drugs for the proposed indication, regulatory status in other countries and justification of Clinical trial waiver as per the provisions of New Drugs and Clinical Trials Rules, 2019 to CDSCO for further review by the committee.
SNDDivision			
3.	SND/MA/21/000089 Omeprazole Delayed release orally disintegrating Tablets 20 mg	M/s Dr Reddy's Laboratories	The firm has presented the proposal of manufacturing and marketing of Omeprazole Delayed release orally disintegrating tablets 20mg along with the BE study protocol.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation the committee recommended for grant of permission for conduct of the BE study as per the protocol presented.
4.	SND/MA/21/000400 Pantoprazole enteric coated delayed release tablets 40 mg (Modified Dosage form),	M/s LUPIN Ltd	The firm has presented the proposal of manufacturing and marketing of Pantoprazole enteric coated delayed release tablets 40 mg (Modified Dosage form) along with the BE study protocol. After detailed deliberation the committee recommended that the firm should submit the detailed rationale for developing this product along with advantage and disadvantage of this proposed formulation over the existing formulation supported by literature.
FDCDivision			
5.	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 proposal before the committee along with the request for Phase III CT waiver. The committee noted that the product is already approved in UK. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing the proposed FDC subject to the condition that the firm is required to conduct PMS study. Accordingly, the study protocol should be submitted within 03 months of the approval.
6.	File No. FDC/MA/21/000125 Acotiamide Sustained Release 300 mg and Rabeprazole Sodium 20 mg Enteric Coated Capsules	M/s. Inventia Healthcare Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee opined that: 1. The firm did not present adequate satisfactory scientific justification along with rationality w.r.t. proposed FDC. 2. It will be difficult to titrate the dose. 3. There are chances of misuse of FDC which will lead to undesirable side effects. 4. FDC is not approved anywhere in the world. 5. This FDC is not recommended in standard treatment guidelines. In view of above, committee did not recommend for approval of the FDC.

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7.	FDC/IMP/20/000088 Poloxamer 407 IH 2.7% + Sodium chondroitin sulphate IH 3.12%+ Sodium hyaluronate IH 1.24% oral liquid	M/s Micro labs Ltd.	The firm presented Phase IV CT protocol before the committee. After detailed deliberation, the committee recommended grant of permission to conduct of Phase IV Clinical trial with condition that proposed sample size should be justified as it appears to be very less.
GCT Division			
8.	CT/53/19 Online Submission (11294) Dated 12/04/21 Etrasimod	M/s. IQVIA	The firm presented the proposedprotocol amendment 3.0 dated 22.02.2021 before the committee. After detailed deliberation, the Committee recommended for approval of the proposed protocol amendment.
9.	CT/88/12 OfflineSubmission (5799) Dated 02/07/21 Tenofovir	M/s. Klinera	The firm presented the proposed protocol amendment 4.1 dated 12.05.2021 before the committee. After detailed deliberation, the Committee recommended for approval of the proposed protocol amendment.
10.	CT/73/21 Online Submission(26690) Dated 01/07/21 Brazikumab	M/s. Astrazeneca	The firm presented their proposal for phase III clinical trial beforethecommittee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trialwith condition that atleast 50 % of the clinical trial sites should be from Govt. Institutions/hospitals.
11.	CT/52/19 Online Submission (11274) Dated 08/04/21 Etrasimod	M/s. IQVIA	The firm presented the proposed protocol amendment 4.0 dated 22.12.202 before the committee. After detailed deliberation, the Committee recommended for approval of the proposed protocol amendment.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
12.	CT/49/2020-DCGI Mirikizumab	--	The firm presented the proposed protocol amendment I6T-MC-AMAM(b) dated 18.12.2020 before the committee. After detailed deliberation, the Committee recommended for approval of the proposed protocol amendment.