Recommendations of SEC (Endocrinology & Metabolism) made in its 88th meeting held on 03.06.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/21/000018 Trelagliptin 50 mg/ 100 mg tablets	M/s. Hetero	In light of earlier SEC recommendation dated 24.11.2021, the firm presented bioequivalence study results before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.
2.	ND/MA/21/000031 Nitisinone 2mg, 5mg and 10mg Capsules.	M/s. Laurus Labs Limited	The firm presented their proposal for grant of permission to manufacture and market Nitisinone 2mg, 5mg and 10mg Capsules along with justification for local clinical trial waiver and BE study waiver, published literature, safety and efficacy data from other countries, advantages and disadvantages of the proposed drug over the available drugs for the proposed indications, regulatory status in other countries, repeated dose toxicity data, dissolution study data etc. The committee noted that Hereditary Tyrosinemia Type I is a very rare disease and there is unmet medical need in the country. The committee also noted that the drug is already approved in US, EU and Australia as an Orphan drug for treatment of Hereditary Tyrosinemia Type I disease and the drug falls under BCS I. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Nitisinone 2mg, 5mg and 10mg capsules with condition that the drug should be sold by retail under prescription of Neonatologist, Pediatrician/Endocrinologist.
3.	ND/MA/22/000083 Imeglimin HCl 500/1000mg tablets	M/s. Mascot Health Pvt. Ltd.	The firm presented their proposal for grant of permission to manufacture and market Imeglimin HCl 500/1000mg tablets along with Bioequivalence study protocol and Phase III clinical trial protocol. After detailed deliberation, the committee recommended that the firm should conduct BE study first and submit BE

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			study results before the committee for further consideration.
4.	ND/MA/22/000063 Sodium Phenylbutyrate Powder	M/s. Laurus	In light of the recommendation of SEC (Reproductive and Urology) dated 24.05.2022, the firm presented their proposal for grant of permission to manufacture and market Sodium Phenyl butyrate powder along with justification for local clinical trial waiver, published literature, safety and efficacy data from other countries, advantages and disadvantages over the available drugs for the proposed indications and regulatory status in other countries. The committee noted that the Urea Cycle Disorder is very rare disease and there is unmet medical need in the country. The committee also noted that the drug is already approved in US, Europe and Canada. After detailed deliberation, the committee recommended for waiver of clinical trial and grant of permission to conduct the BE study. Accordingly, the firm should submit the results of the BE study for further review by the committee.
SND Division			
5.	SND/MA/22/000149 Liraglutide 6mg/ml solution for injection in prefilled Pen (18mg/3ml pre-filled Pen)	M/s. Biocon Pharma	The firm presented their proposal of exploratory BE study protocol of Liraglutide 6mg/ml solution for injection in prefilled pen (18mg/3ml prefilled pen) (synthetic peptide) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct respective exploratory BE study as per the protocol presented.
BA/BE Division			
6.	12-09/2022/BA-BE/Misc-04/DC Vildagliptin 50 mg, Metformin HCl 500 mg, Pioglitazone	M/s. Ajanta Pharma	The firm presented their proposal of Bioavailability/Bioequivalence Study of Vildagliptin 50 mg, Metformin HCl 500 mg, Pioglitazone 15mg for export purpose before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study subject to the condition that a second screening before

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			the third period should be conducted. Accordingly, the firm should revise the BE study protocol and submit the same to CDSCO.