Recommendations of the SEC (Endocrinology & Metabolism) made in its 109th meeting held on 14.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000030 Cholecalciferol Oral Suspension 400 IU/5ml (Additional Indication & Additional Dosage Form)	M/s. Stedman Pharma Private Limited	In light of earlier SEC recommendations dated 23.11.2023. Firm presented justification for waiver of bioequivalence study & clinical trial before the committee in presence of pediatric expert. After detailed deliberation, the committee noted that the firm has not shown clinical relevance of proposed strength in pediatric population. Hence, the proposed strength Cholecalciferol oral suspension 400 IU/5ml may not be considered for approval.
2.	SND/MA/23/000032 Cholecalciferol Oral Suspension 800 IU/5ml (Additional Indication & Additional Dosage Form)	M/s. Stedman Pharma Private Limited	In light of earlier SEC recommendations dated 23.11.2023. Firm presented justification for waiver of Bioequivalence study & clinical trial before the committee in presence of pediatric expert. The firm informed that the similar formulation Cholecalciferol oral drops 800IU/ml already approved by the CDSCO on 08.03.2021. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Cholecalciferol oral suspension 800 IU/5ml (Additional Indication & Additional Dosage Form) with BE & CT waiver. However, In addition to the above, firm should fulfill the requirements of CMC data.
3.	SND/MA/23/000029 Cholecalciferol Oral Drops 400IU/ml	M/s. Stedman Pharma Private Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Cholecalciferol oral drops 400IU/ml (Additional Strength) along with justification for waiver of bioequivalence study & clinical trial study before the committee. The firm informed that the Cholecalciferol oral drops 800IU/ml already approved by the CDSCO on 08.03.2021. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of

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			Cholecalciferol oral drops 400IU/ml with BE study & CT study waiver. However, In addition to the above, firm should fulfill the requirements of CMC data.
4.	SND/MA/22/000235 Alpha Lipoic Acid Solution for injection (Intravenous Infusion 25 mg/ml(600mg/24ml) (Additional Dosage form)	M/s La Renon Healthcare Private Limited	In light of earlier SEC recommendation dated 21.12.2022, firm presented justification for waiver of local CT study before the committee. The firm informed that the similar formulation already approved in other countries like Germany and USA as a dietary supplement. After detailed deliberation, the committee opined that the limited clinical trial is required to be conducted in Indian population to prove the safety and efficacy, the proposed formulation being injectable formulation. Accordingly, the firm should submit comparative clinical trial study protocol to CDSCO for further review by the committee.
FDC Division			
5.	FDC/MA/23/000085 Lobeglitazone sulfate 0.25mg/0.25mg + Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin 50mg/100mg film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm did not turn up for presentation.
6.	FDC/MA/23/000222 Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. Sitagliptin (10mg+100mg/ 25mg+100mg) film coated tablets	M/s. Torrent Pharmaceuticals Ltd.	In the light of earlier SEC recommendation dated 27.09.2023& 29.09.2023, firm presented their proposal along with revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the revised protocol. The firm should submit Phase III clinical trial report to CDSCO for further review by the committee.

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7.	FDC/MA/23/000273 DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin 5mg + Linagliptin 2.5mg film coated tablet	M/s. Synokem Pharmaceutical Ltd.	The firm presented their proposal along with request for BE study & Phase III clinical trial study waiver for lower strength based on the Clinical Trial report of higher strength i.e. Dapagliflozin 10mg + Linagliptin 5mg film coated tablet and supporting literature for lower strength before the committee. The committee noted that the FDC of Dapagliflozin 10mg + Linagliptin 5mg film coated tablet is already approved by CDSCO on 03.07.2023. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC in lower strength i.e. Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg + Linagliptin 2.5mg film coated tablet.
GCT Division			
8.	CT/174/22 Online Submission (29789) CagriSema 2.4 mg/2.4 mg s.c.	M/s. Novo-Nordisk	The firm presented protocol amendment, version 6.0 dated 14 September 2023, protocol No. NN9838-4942. After detailed deliberation, the committee recommended for approval of the protocol amendment and increase in numbers of subjects from 264 to 642 as presented by the firm.