Recommendations of the SEC (Reproductive) made in its 05th/25 meeting held on 20.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-79599 Trinbelimab (Recombinant Anti Rho-D Immunoglobulin)	M/s Syngene International Limited	The firm did not turn up for the presentation.
New Drug Division			
2.	ND/IMP/25/000006 Fezolinetant 45 mg film-coated tablets	M/s Astellas Pharma India Pvt. Ltd	The firm presented the proposal for grant of permission to import and market of new drug Fezolinetant 45 mg film-coated tablets with justification for local Phase III clinical trial waiver before the committee. After detailed deliberation, the committee opined that the major reported adverse event with drug Fezolinentant is elevation in the liver enzyme which is indicative of variation in the metabolism of drug Fezolinentant in different population. The committee noted that there is no unmet medical need and did not consider the waiver of Phase III clinical trial. Accordingly, the firm should submit the Phase III clinical trial protocol before the committee for further consideration.
3.	ND/CT/25/000029 Elagolix Sodium Tablets 150 mg & 200 mg	M/s Exemed Pharmaceuticals	In line with the condition of the permission for the manufacturing and marketing of the drug Elagolix Tablets 150mg/200mg, the firm presented Phase IV clinical trial protocol for drug Elagolix Tablets 200mg, before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct Phase IV clinical trial as per the protocol presented. The results of the Phase IV Clinical Trial should be submitted to CDSCO, for further review by the committee.

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SND Division			
4.	SND/IMP/24/000121 Levonorgestrel 75mg Implant	M/s Bayer Pharmaceuticals Pvt. Ltd.	Firm presented their proposal for Import and Marketing of Levonorgestrel 75 mg Implant for the indication contraception with request for clinical trial waiver. Firm has informed that the proposed product is marketed in 53 countries and presented published literature of Phase II and III clinical trial studies conducted by ICMR approx 40 years ago. The Committee noted that, the product was withdrawn from many countries including USA, Germany, France, Indonesia for which firm has not provided adequate rationale for the withdrawal of product from regulated countries. Further the study data presented by the firm does not support the efficacy and release of drug from implant and no regulatory approval was sought for the same. After detailed deliberation, the committee recommended that, the data presented by the firm is not adequate to support safety and efficacy of proposed product. Hence, the committee did not consider the proposal for import and marketing of Levonorgestrel 75 mg Implant.
5.	SND/MA/24/000148 Magnesium Sulfate in 5% Dextrose Injection USP (10Mg/ml)-100ml plastic bottle	M/s Otsuka Pharmaceutical India Private Limited	Firm has presented proposal for the manufacturing and marketing of Magnesium Sulfate in 5% Dextrose Injection USP (100 mg/ml) 100 ml bottle for indication prevention and control of seizures in pre-eclampsia and eclampsia respectively with clinical trial waiver. Firm presented that, applied strength is approved in US since 1941 but the package insert is revised in 2020. Experts stated that, administration of 100 ml of Magnesium Sulfate in 5% Dextrose Injection makes it 2400 ml per day which

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			is not justified and may lead to pulmonary oedema in pre-eclampsia and eclampsia patients. After detailed deliberation, committee stated that, firm should present the global approved PI, more justification in support of the proposed dose to be presented before the committee for further review.
FDC Division			
6.	04-01/2019-DC (Misc. 53) Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet	M/s. IPCA Laboratories Ltd.	In light of earlier SEC recommendation dated 18.12.2024, the firm presented the proposal along with revised Active PMS protocol number 1 and 2 before the committee. After detailed deliberation, the committee recommended to conduct the Active PMS study of protocol number 1 with condition that Point 2 of inclusion criteria to be replaced by "Patients with normal gynecological examination and or normal ultrasound findings of uterus and adnexa." As regards to Protocol number 2, the committee opined the following: 1. Basic investigation like ultrasound should define the diagnosis of biliary or ureteric colic. 2. Basic investigations like CBC, RFT, LFT, and ECG at baseline and at the end and whenever required. Accordingly, for Protocol number 1, the revised Active PMS Protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Active PMS report for further review by the committee. Further, for Protocol number 2, the firm should submit revised Active PMS protocol to CDSCO for further review by the committee.
7.	FDC/MA/22/000418 Estradiol (as	M/s. Akums Drugs & Pharmaceuticals	In light of the earlier SEC recommendation dated 26.04.2023, the firm presented the proposal along with

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	hemihydrate) USP Eq. to Anhydrous Estradiol 0.5mg/1.0mg + Drospirenone IP 0.25mg/0.5mg tablets	Ltd.	BE study report and justification for Phase III CT waiver before the committee. The committee noted that the said FDC is already approved in the USA, UK, Germany, France, etc. After detailed deliberation, the committee considered the BE study report as well as the request for Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC with the condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.
8.	FDC/MA/25/000021 Relugolix, Estradiol and Norethindrone Acetate tablets(40mg+1mg+0.5 mg)	M/s. Zydus Healthcare Limited	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct BE study. Accordingly, the firm should submit the BE study report along with Phase III CT protocol to CDSCO for further review by the committee.