Recommendations of the SEC (Reproductive) made in its 11th meeting held on 18.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	r-DNA-11011/1/2024-eoffice Follicle Stimulating Hormone I.P. 300IU and 600IU	M/s. Organon India Pvt. Ltd.	The firm presented the proposal for update in package insert of the drug product Follicle Stimulating Hormone I.P. 300IU and 600IU to include safety update in Section of Undesirable Effects based on the updated CCDS version S-CCDS-OG8328-SOi-082023 dated August 2023. After detailed deliberation, the committee recommended for approval of updated Package insert version ORGIN 01/2024 of Follicle Stimulating Hormone I.P. 300IU and 600IU.
SND Division			
2.	SND/MA/24/000101 Dydrogesterone injection 5mg/ml	M/s Mankind Pharma Private Limited	In light of earlier SEC (reproductive) recommendation dated 04/07/2024, the firm presented protocol for the Phase Ib/II clinical trial (part A - Protocol No. SLS-CL-0083-24-DYDR version No. 01 dated 30/09/2024 and Part B - Protocol no.: ECTS/24/009, Version 00, Dated 01 Oct 2024). After detailed deliberation, the committee recommended to conduct the Phase Ib part A clinical study as per the protocol presented. The committee also recommended to include complete lipid profile and coagulation profile during pre-study/screening and post study assessment to assess the progesterone (dydrogesterone) induced changes in the protocol presented and submit the revised protocol to the CDSCO. After conduct of Phase Ib part A study, outcomes of the Phase Ib part A study shall be presented before the committee before proceeding to the next step of proposed study.

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FDC Division			
3.	04-01/2019-DC (Misc. 53) Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet	M/s. IPCA Laboratories Ltd.	In light of earlier SEC recommendation dated 16.05.2024, the firm presented the proposal along with revised Active PMS protocol before the committee. After detailed deliberation, the committee opined that - 1. Differentiation between primary and secondary dysmenorrhea should be mentioned in the inclusion criteria. 2. Dosage schedule (timing, initiation and duration of the drug) should be defined. 3. Assessment criteria including uniformity in pain scale. 4. Scientifically defined calculation of sample size. 5. More number of government sites should be included in the study protocol no.1. As regard the protocol no.2, the committee recommended that the experts from urology and gastroenterology should be included in the next SEC meeting. Accordingly, firm should submit revised protocol no.1 along with protocol no.2 to CDSCO for review by the committee.
4.	FDC/MA/23/000330 Relugolix 40 mg + Estradiol Hemihydrate Eq. to Estradiol USP 1 mg + Norethindrone Acetate 0.5 mg Tablets	M/s Macmillon Pharmaceuticals Pvt. Ltd.	In light of the earlier SEC recommendation dated 21.08.2024, the firm presented the proposal along with revised Phase III CT Protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III CT Study with following condition: 1. In the comparator arm Leuprolide dose should be mentioned. 2. Estradiol Hemihydrate + Norethindrone Acetate should be added in the comparator arm. 3. Pelvic ultrasound and BMD (Bone Marrow Densitometry) test should be done at the time of screening and after 12

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			weeks at the end of the study. Accordingly, the revised phase III CT protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase III CT report for further review by the committee.