Recommendations of the SEC (Reproductive & Urology) made in its 89th meeting held on 19.12.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000113 FDC of Relugolix, Estradiol and Norethindrone Acetate Tablets (40 mg + 1 mg + 0.5 mg)	M/s. Sun Pharmaceutical Industries Limited	The firm presented their proposal of Phase-III clinical trial waiver for grant of permission to manufacture and market FDC of Relugolix, Estradiol and Norethindrone Acetate Tablets (40 mg + 1 mg + 0.5 mg) along with BE study report. After detailed deliberation the committeenoted that there is no safety & efficacy data on Indian population. Hence, committee recommended that the firm should conduct Phase-III clinical trial for the proposed indication and accordingly, the firm should submit the clinical trial protocol to CDSCO for further consideration.
SND Division			
2.	SND/IMP/23/000064 Triptorelin Powder for injection 3.75mg	M/s. Dr. Reddy's Laboratories	The firm presented their proposal for grant of permission (additional Indication) for the management and relief of chronic pain associated with endometriosis for the drug Triptorelin powder for injection 3.75mg along with justification for Bio and CT waiver before the Committee. The Committee noted that the firm has not provided Indian population data for proposed additional indication. After detailed deliberation, the Committee recommended that the firm should conduct Phase-III clinical trial for proposed additional indication for which the firm should submit Phase-III clinical trial protocol to CDSCO for further review by the Committee.
3.	SND/MA/23/000234 FlavoxateHCl SR Tablets 600mg	M/s. Ravenbhel Healthcare Pvt. Ltd.	The firm presented their proposal for grant of permission to manufacture and marketing of FlavoxateHCl SR Tablets 600mg (additional strength) along with Clinical trial and Bioequivalence protocol before the Committee.

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			The Committee noted that the Flavoxate HCl SR Tablets 100mg already approved by the CDSCO in year 1981. After detailed deliberation, the Committee recommended that the firm should conduct Bioequivalence Study as per protocol presented by the firm and submit revised CT protocol with clearly defined objective, end points, inclusion & exclusion criteria, safety, efficacy parameters to be assessed etc. for review by SEC.
FDC Division			
4.	FDC/MA/22/000421 Norethindrone Acetate USP 0.5mg + Estradiol (as Hemihydrate) USP eq. to Anhydrous Estradiol 1mg + Relugolix 40mg film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 31.01.2023 & 30.08.2023, the firm presented their proposal along with justification for CT waiver before the committee. After detailed deliberation the committee noted that there is no safety & efficacy data available on proposed FDC in Indian population. Hence, committee recommended that the firm should conduct Phase-III clinical trial for the proposed indication. Accordingly, the firm should submit the clinical trial protocol to CDSCO for review by the committee.