Recommendations of the SEC (Reproductive & Urology) made in its 70th meeting held on 24.05.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000045 Sodium Phenylbutyrate Powder 940 mg	Ms. Laurus	In light of the earlier SEC recommendation dated 27.04.2022, the firm presented the proposal before the committee. The proposal was deliberated in presence of Nephrologist and Pediatrician. After detailed deliberation, the committee noted that the proposal needs to be deliberated in SEC (Endocrinology and Metabolism) along with Nephrologist, Pediatrician and Neonatologist.
FDC Division			
2.	4-66/2018-DC (Pt. Akums) Alfuzosin Hydrochloride IP (as Extended Release) 10mg/10mg + Tadalafil IP 2.5mg/5mg film coated tablets	M/s. Akums Drugs & Pharmaceuticals	In light of earlier SEC recommendation dated 25.03.2022, the firm presented raw data of BE study report. After detailed deliberation, the committee recommended for initiation of Phase III CT study and the firm should present Phase III CT study report for consideration by the committee.
Medical Device Division			
3.	CI/MD/2021/50341 Disposable Circumcision Suture Device (LANGHE)	M/s. V M Meditech Pvt. Ltd	The firm presented their proposal for Post Marketing Clinical Investigation of the proposed device before the committee. After detailed deliberation, the committee recommended for approval of the amendment of the clinical investigation protocol with respect to the following: 1. Sample size should be 200 patients. (100 –Adult, 100-Children). 2. Clinical investigation sites should be 10 in number geographically distributed in the country. Out of that atleast 50 % should be government institutions. Accordingly, the firm should submit revised clinical investigation protocol to CDSCO for further review by the committee.
4.	IMP/MD/2021/38932	M/s. Morulla Health Tech Pvt.	In light of earlier SEC recommendation dated 24.03.2022, the firm presented their

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Pessary Ring Flexible Vinyl (PORTIA)	Ltd.	proposal for import and marketing of the proposed device before the committee. The committee observed that the firm has not presented long term safety and efficacy data of the proposed product. After detailed deliberation, the committee recommended that the firm should submit long term safety and efficacy data and package insert of the proposed product for further review by the committee.