Recommendations of the SEC (Neurology & Psychiatry) made in its 79th meeting held on 20.04.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000124 Vigabatrin Powder for oral solution 500 mg	M/s. MSN Laboratories Ltd	In light of earlier recommendation of SEC dated 13.10.2020 and 14.10.2020, the firm presented the PMS study protocol before the committee. The committee observed various lacunae in the PMS study protocol. After detailed deliberation, the committee opined the following:- 1. The firm should redefine the primary and secondary outcome of the protocol. 2. The firm should define parameters of ECG, ophthalmologic evaluation and the screening instruments and scales for psychiatric adverse effects including psychological/psychiatric assessment for children 3. The firm should define range for population, age and dosage for adult patients as well as pediatric patients correctly. 4. Justification for sample size calculation should be given by the firm. Accordingly, the firm should submit revised PMS study protocol as recommended by the committee for further deliberation.
SND Division			
2.	SND/MA/22/000091 Brivaracetam Sustained Release Tablet 200mg	M/s. Ravenbhel Healthcare	The firm presented the BE study protocol before the committee for approval. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol presented.
FDC Division			
3.	FDC/MA/22/000068 Silodosin 8 mg+ Solifenacin Succinate 5mg Tablets	M/s. Savi Health	The firm didn't turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	FDC/MA/21/000267 Naloxone Hydrochloride eq. to Naloxone + Buprenorphine Hydrochloride eq. to Buprenorphine (0.25mg+ 1mg) Tablets	M/s. Rusan Pharma Ltd	In light of earlier SEC recommendation dated 16.12.2021, the firm presented their proposal along with the justification. The committee noted that the higher strength of the FDC is already approved and the proposed lower strength of the FDC will be helpful in titrating the dose. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
5.	FDC/MA/22/000082 Clonazepam 0.25mg + Desvenlafaxine 50mg (Extended Release) Tablets	M/s. Pure & Cure	In light of the earlier SEC recommendation dated 17.09.2020 and 18.09.2020, the firm presented their proposal along with the justification and BE study protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The results of the BE study should be presented before the SEC.
GCT Division			
6.	CT/122/20 Online Submission (15385) Galcanezumab	M/s. Eli Lilly	The proposal is deferred for next SEC meeting.
7.	CT/123/20 Online Submission (15384) Galcanezumab	M/s. Eli Lilly	The proposal is deferred for next SEC meeting.