Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 123rd meeting held on 06.11.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/20/000302 Favipiravir Chewable Tablets 800 mg/1800 mg	M/s. Macleods Pharma	The firm presented the proposal of manufacturing and marketing of Favipiravir Chewable Tablets 800mg & 1800mg before the committee. In light of the fact that the Favipiravir is approved for restricted emergency use with various conditions and restrictions, the committee observed that justification submitted by the firm in support of Chewable tablet is inadequate. Hence, after detailed deliberation, the committee did not recommend for approval of Favipiravir Chewable Tablets 800 mg/1800 mg
FDC Division			
2.	FDC/CT/20/000075 Favipiravir + Bromhexine tablet; Favipiravir + Colchicine USP tablet; Favipiravir + Nitazoxanide tablet	M/s Mylan Laboratories Limited	The firm presented the 4 arms trial protocol before the committee. After detailed deliberation, committee recommended that the firm should submit the following– 1. Scientific justification for having four arms with different drugs in the proposed study. 2. In the proposed trial of 4 arms, Favipiravir with 3 different drugs is proposed to be compared with SOC. Justification for comparing the combination therapy vs SOC instead of comparing the combination therapy with Favipiravir + SOC should be submitted. 3. Justification for defining the study as Phase IIb CT. The firm should submit above information for further consideration by the committee.
New Drug Division			
3.	ND/IMP/20/000058 Themis Pranobex	M/s. Themis Medicare Ltd.	The firm presented their proposal for approval of the drug along with the report of Phase II, proof of concept clinical study of Inosine Pranobex tablets in mild to moderate COVID before the committee.

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			The committee observed that the results of the study presented by the firm are inadequate for approval of the drug. After detailed deliberation, the committee did not recommend for approval of the drug in COVID, based on the data presented.