Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 119th meeting held on 22.10.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/20/000290 Favipiravir Tablets 800 mg/200 mg Combi-Pack	M/s Hetero Labs	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Combi-pack of Favipiravir Tablets 800 mg (16 tabs) and Favipiravir Tablets 200 mg (2 tabs) for the earlier approved indication along with conditions/ restrictions stipulated in the permissions granted for Favipiravir Tablets 200mg/400mg/800 mg.
FDC Division			
2.	FDC/MA/20/000148 Combipack for Daclatasvir and sofosbuvir tablets 60mg/400mg + Nitazoxanide tablets 500mg.	M/s Mylan	The Committee recommended that request of the firm for grant of permission for manufacturing and marketing the proposed Combipack will be considered once all the study data are generated by the firm and rewind by the committee. At present the proposal may not be considered for approval of the combipack.
3.	FDC/MA/20/000103 Daclatasvir Dihydrochloride IP equivalent to Daclatasvir 60mg +Sofosbuvir 400mg film-coated tablet	M/s Mylan	Firm Presented the amended protocol before the committee. After detailed deliberation committee recommended for grant of permission to conduct the proposed Phase II Clinical Trial with the following conditions: 1. Upper age limit should not be more than 65 years. 2. DSMB shall be appointed by Sponsor 3. More Govt. Sites should be included and the sites should be geographically distributed. The results of the study shall be presented before the committee for further review.
New Drug Division			
4.	12-01/18-DC(Pt-337) Hydroxychloroquine used for management of situation arising	Internal Discussion	The ICSR reported by PvPI was deliberated by the committee. After detailed deliberation the committee opined that CDSCO should communicate to the PvPI to further examine if any other reported ADR has

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	due to COVID-19		been received by them for taste disorder and urinary incontinence. If so, details should be obtained for further consideration.