Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 109th meeting held on 14.09.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/20/000076 Favipiravir 200 mg tablets	M/s. Dr. Reddy	The firm presented their proposal for Phase IV Clinical Trial. After detailed deliberation the committee recommended for conduct of Phase IV Clinical Trial subject to the following condition: 1. 50% of Govt site should be included for the study. 2. Physician actively involved in treating COVID-19 patients to be included in the study at various sites. 3. Standard of Care across all the sites should be standardised as far as practicable. 4. Active monitoring of the patient safety should be reported to CDSCO.
2.	12-01/18-DC (Pt-337) Hydroxychloroquine Tablets	PvPI	The committee deliberated the recommendation of the PvPI. However, the committee opined that the ICSRs to be examined in detail along with safety data available in the public domain.
SND Division			
3.	SND/MA/20/000206 Favipiravir 600/800 mg tablets	M/s. Hetero Labs	In light of earlier SEC recommendation dated 25.08.2020, the firm presented their proposal only for Favipiravir Tablets 800mg. After detailed deliberation the committee recommended for grant of permission for manufacture & market Favipiravir Tablets 800mg only with same conditions and restrictions stipulated for 200 mg and 400 mg tablets.
FDC Division			
4.	FDC/MA/20/000103 Daclatasvir Dihydrochloride IP equivalent to Daclatasvir 60mg +Sofosbuvir 400mg film-coated tablet	M/s Mylan	In light of the recommendations of the SEC dated 02.09.2020, firm presented their proposal before the committee. After detailed deliberation, committee opined that: 1. Firm could not provide statistical justification for the sample size of 268 subjects for conducting the proposed Phase III clinical trial. 2. It will not be appropriate to include

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			mild patients in the proposed study. 3. It will not be desirable to have direct Phase III trial just based on two Iranian studies which were just investigator initiated studies and not approved by Iranian, FDA. Further the FDC of Daclatasvir +Sofosbuvir is also not approved internationally for the treatment of COVID-19 patients. 4. It will be appropriate initially to conduct phase II Trial on moderated COVID-19 patients with the proposed design in place of Phase III trial. In view of above, committee recommended that, firm should address the above points for further deliberation by the committee.