Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 104th meeting held on 25.08.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/20/000051 C21	M/s QED	The firm presented their protocol amendment before the committee. After detailed deliberation Committee recommend for approval of the proposed protocol amendment version-02. However, Firm should submit MHRA, UK approval of the proposed protocol amendment, when available.
2.	CT/73/20-DCG(I) Ruxolitinib 5 mg	M/s Novartis	Firm did not turn-up for presentation.
Subsequent New Drug Division			
3.	SND/MA/20/000212 Favipiravir Tablets 800 mg	M/s Cipla	The firm presented their proposal for Favipiravir Tablets 800 mg before the committee. Favipiravir tablets 200mg & 400mg are already approved for restricted emergency use in India. After detailed deliberation, the committee recommended that the firm should submit detailed clinical justification for the proposed strength of Favipiravir alongwith supportive literature and updated clinical data from other countries as available for further consideration.
4.	SND/MA/20/000206 Favipiravir Tablets 600&800 mg	M/s Hetero	The firm presented their proposal of Favipiravir Tablets 600 & 800 mg before the committee. Favipiravir tablets 200mg & 400mg are already approved restricted emergency use in India. After detailed deliberation, the committee recommended that the firm should submit detailed clinical justification for the proposed strengths of Favipiravir alongwith supportive literature and updated clinical data from other countries as available for further consideration.
5.	SND/MA/20/000191 Remdesivir Sublingual Tablets 20 mg	M/s Jubliant	The firm presented their proposal along with bioavailability protocol before the committee. After detailed deliberation, the committee recommended that the firm should submit clear justification for use

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			of the drug through sub-lingual route supported by evidence/literature including animal PK data generated with the drug through sub-lingual route.
6.	SND/MA/20/000219 Glutathione for injection 600 mg (Additional indication)	M/s Zuventus Healthcare Ltd	The firm presented their proposal along with proof of concept study protocol before the committee. After detailed deliberation, the committee recommended that the protocol should be revised as under: 1. The study should be a randomized, double blind , placebo controlled proof of concept trial, with, with SoC in both the arms. 2. The inclusion and exclusion criteria should be clearly defined for moderate COVID-19 patients as per Government of India guidelines. 3. The Primary end points should include clinical improvement based on WHO ordinal scale 4. SoC in different sites should be standardized as far as practicable. Accordingly, the firm should submit the revised protocol for further consideration by the committee.