Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process held on 07.05.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT-21/2020/19176 Aqueous Extract of Cocculus Hirsutus AQCH	M/s Sun Pharma	The firm presented their proposal for grant of permission to conduct randomized Phase II clinical trial with revised protocol in light of recommendations of the SEC meeting dated 28.04.2020. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase II clinical trial subject to following conditions 1. Symptoms of respiratory system like fever, cough etc. should be included in the inclusion criteria. 2. Safety analysis should be done by DSMB on enrolment of 40 patients and also 100 patients in the study. Accordingly, firm should submit the revised protocol to CDSCO before initiation of the study.
2.	ND/CT-21/BO/2020/19309 Favipiravir Tablets 200 mg	M/s Cipla Ltd, Mumbai	The firm presented their proposal for grant of permission to conduct randomized Phase III clinical trial. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Clinical Trial subject to the condition that, RT-PCR testing should be done every alternate day starting from day 04. The committee further opined that the approval of the drug for COVID-19 treatment will be based on the data generated from this Clinical Trial as well as clinical data available from other countries at that point of time.
3.	ND/CT-21/000038 Nano scale metallic antiviral immunomodulatory formulation Gold, Copper, Zinc	M/s Rasayani biological Pvt Limited	The firm presented their proposal for grant of permission to conduct randomized Phase III clinical trial. Committee noted that the justification presented was not adequate for conduct of Phase III Clinical trial. After detailed deliberation, the committee recommended that the firm should submit the detailed Safety and efficacy data generated with their product including preclinical data and

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			safety data in support of its use in the trial in co-morbid patients with COPD, diabetes, cardiac diseases etc. The above data should be presented along with Phase-II clinical trial proposal with justification for dose, duration of treatment etc. for review by the committee.
Subsequent New Drug Division			
4.	SND/CT/20/000007 Hydroxychloroquine, Niclosamide, & Nitazoxanide, Combination of Hydroxychloquine & Nitazoxanide & Combination of Niclosamide & Nitazoxanide	Dr. Reddy's Laboratories Limited	The firm presented their proposal for grant of permission to conduct randomized Phase II clinical trial with revised protocol in light of recommendations of the SEC meeting held on 24.04.2020. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II clinical study subject to following conditions: 1. The study should be a Two arm study as HCQS Vs HCQS + Nitazoxanide in moderate CoVID-19 patients with 75 patients in each arm. 2. Criteria for moderate CoVID-19 patients should be clearly defined in the inclusion criteria as per ICMR or MoHF&W, Govt of India guidelines. 3. There should be no interim analysis for efficacy. 4. Detailed criteria for safety assessment should be specified. 5. There should be DSMB for monitoring of safety. Revised protocol should be submitted to CDSCO prior to initiation of the study.
5.	12-01/2020-DC (Pt-NSRT-SND) Eflornithine granules 2.56 g & 5.0 gm	M/s Navin Saxena Research technology	The applicant presented their proposal to conduct Phase IIb Clinical Trial along with supportive documents & protocol. After detailed deliberation the committee recommended that the firm should submit detailed data of *in-vivo* / *in-vitro* antiviral activity of the drug and conduct the PK & safety study of oral Eflornithine granules in human or submit data if available to consider the matter further.
Biological Division			

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6.	BIO/CT04/FF/2020/19586 Pegylated Interferon alpha 2b	M/s Cadila Healthcare Limited	The firm presented their proposal for grant of permission to conduct randomized Phase II clinical trial with revised protocol in light of recommendations of the SEC meeting dated 04.05.2020. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase II clinical trial subject to following conditions - (1) Standard of care should be uniform to the fullest possible extent across both the arms throughout the trial. The same should be submitted to CDSCO before initiation of the trial. (2) Criteria of moderate patients as per ICMR should be included in the inclusion criteria Accordingly, firm should submit the revised protocol to CDSCO before initiation of the study. (Dr. Ananta Mohan did not participate in the deliberation).
7.	BIO/CT/20/000051 (Tocilizumab)	JSS Medical Research India Pvt. Ltd.	The firm presented their proposal for grant of permission to conduct randomized Phase III clinical trial with revised protocol in light of recommendations of the SEC meeting held on 04.05.2020. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase II clinical trial.