Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 115th meeting held on 09.10.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/20/00028 Composition of biocompatible calcined nano scale Zinc+ Biocompatible calcined nano-scale copper + Detoxified and Biocompactible calcined nano-scale Arsenic	M/s. Rasayani	The firm presented their proposal be for conduct of Phase II Clinical Trial before the committee. After detailed deliberation committee recommended that the firm should follow the appropriate drug development pathway. Accordingly, firm should submit the phase I clinical trial protocol to CDSCO with the adequate justification for individual ingredients as well their combination, dose, duration of treatment etc. for review by the committee.
2.	12-01/20-DC (Pt-339) N-Acetylcysteine	M/s. Index Medical College	Applicant presented their proposal before the committee. During the presentation the committee was informed that the trial has been already initiated after ethics committee approval. The committee recommended that CDSCO should ask the ethics committee for reason for their communication to CDSCO for the trial.
3.	12-01/20-DC (Pt-116) Solidarity Trial	ICMR-NARI	The applicant presented for amendment in the protocol, including addition of one new arm of Acalbrutinib in Solidarity trial before the committee. The committee after detailed deliberation opined the following: 1. At present, Remdesivir and Dexamethasone are used as part of treatment in such COVID patients. However, as per the proposal, such patients included in Acalabrutinib arm may not receive these drugs. 2. One Global clinical trial of Acalbrutinib is ongoing in various countries including India. 3. During the presentation, the committee was informed that the results on Remdesivir from the Solidarity trial may be available in few weeks. In view of above, the committee after detailed deliberation recommended that more clarification/justification for inclusion of Acalabrutinib arm in the Solidarity trial will be required before including the arm at present.
4.	ND/CT04/FF/2020/1977 3 Favipiravir &	M/s Glenmark	The firm presented the result of the clinical trial before the committee. From the results it was observed that there is no

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Umifenovir		superiority of Favipiravir + Umifenovir combination over Favipiravir alone. The firm has also decided to withdraw their proposal for market authorization of the combination. The committee however recommended that CDSCO should obtain the details of one SAE (death) reported and presented before the committee, including analysis of ethics committee, investigator & sponsor etc for review as per the requirements.
GCT Division			
5.	CT/96/2020 Allokin Alpha®, Lyophilisate Subcutaneous Injection	M/s. Prorelix Service LLP	The firm presented their Phase II clinical trial protocol before the committee. After detailed deliberation the committee opined that the data presented by the firm for Phase II is not adequate. Therefore, the committee recommended that the firm should submit non clinical efficacy data against COVID-19 & PK data of Phase 1 study to consider the matter further. Dr. Abhisek Aggarwal did not participate in the deliberation.
6.	CT/89/20-DCGI Severe Acute Respiratory syndrome Coronavirus (SARS-Cov-2)	M/s. PPD	The firm presented their proposal for conduct of the Part 1study protocol before the committee. After detailed deliberation the committee opined that the justification and feasibility to conduct part 1 of the study in India was not adequate. Therefore, committee did not recommend for approval of the proposed part 1 study of the protocol.
SND Division			
7.	SND/MA/20/000284 Remdesivir for injection	M/s. Mylan	The firm presented the proposal for permission to expand the indication of Remdesivir. After detailed deliberation the committee recommended for the grant of permission for the expansion of the indication for moderate COVID-19 patients in addition to already approved indication.