Recommendations of the SEC meeting to examine COVID-19 related proposals under accelerated approval process made in its 118th meeting held on 20.10.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/20/000159 Inactivated Corona Virus Vaccine (BBV152) (Protocol version 2.0 dated 12.10.2020)	M/s Bharat Biotech Ltd., Hyderabad	In continuation of the SEC meeting dated 05.10.2020, firm presented their data from Phase I and II along with animal challenge data in two species including NHP on the Inactivated Corona Virus Vaccine (BBV152) along with the proposal to conduct event driven Phase III clinical trial to assess the efficacy of the vaccine. After detailed deliberation and based on the available evidences, the committee recommended for grant of permission to conduct Phase III clinical trial subject to the condition that the Primary efficacy endpoint for symptomatic cases should be amended as below: • Once a suspect case is confirmed the PI will evaluate the clinical information to classify it as a symptomatic case. • Two Criteria must be met for a participant to be a confirmed symptomatic case. Either criteria A or B with positive RT-PCR confirmation. • Criteria A: One or more - Shortness of Breath/Difficulty in breathing, New onset Anosmia/Aguesia, Oxygen saturation of <94% or escalation in supplemental O2, Pneumonia diagnosed by chest X ray or CT scan, Evidence of Shock, ICU Admission/Death OR • Criteria B: Two or more - Fever, Chills, New cough, Myalgia/Fatigue, Headache, Sore throat, Nausea/Vomiting, Diarrhea, Congestion/ Runny Nose. The events not meeting the primary endpoint shall be categorized as

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			secondary endpoints.
New Drug Division			
2.	12-01/20-DC (Pt-116) WHO Solidarity Trial	ICMR-NARI	The applicant presented interim analysis results of WHO - Solidarity trial along with proposal for dropping of interferon arm and addition of Acalabrutinib arm in the study. After detailed deliberation committee recommended that the applicant should present the latest version of protocol, before the committee for further deliberation. Dr. Abhishek Agrawal did not participate in the deliberation.
3.	ND/MA/20/000040 Colloidal silver 50ppm hand sanitizer	M/s Nanz Med Sciences Pvt. Ltd.	Firm presented clinical evaluation study of Colloidal silver 50ppm hand sanitizer before the committee. After detailed deliberation the committee recommended that the firm should submit details of other marketed Colloidal silver hand sanitizer. Further the firm should submit literature/data on safety studies of Colloidal silver 50ppm products approved in other countries and also submit do's & dont's , Label, package insert to Committee for further consideration.