Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 114th meeting held on 05.10.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/20/000066 Sodium Copper Chlorophyllin	M/s IDRS	In light of the SEC recommendation the firm has presented the response before the committee. After detailed deliberation the committee recommended for grant of permission for conduct of Phase II Clinical Trial subject to the following conditions: 1. Viral clearance and clinical progression based on WHO ordinal scale should be primary end point. 2. Cytokinine assessment and all-cause modality should be secondary end point along with safety assessment etc. The results of the Phase II Clinical Trial should be submitted CDSCO for review and consideration.
2.	ND/MA/20/000083 Remedesivir for injection 100 mg/vial	M/s Jubliant Generics Limited	Firm presented their proposal before the committee. After detailed deliberation the committee recommended for approval for conduct of PMS study. The firm should submit the details of the study centers to CSDCO.
3.	12-01/20-DC (Pt-339) N-Acetylcysteine	M/s Index Medical College & Research Center	The firm didn't turn up for the presentation.
Biological Division			
4.	BIO/CT/20/000150 SARS-CoV-2 Equine Antiserum Immunoglobulin	M/s Biological E Ltd., Hyderabad	Firm presented their protocol for conduct of Phase I clinical trial along with non-clinical toxicity data. The committee after detailed deliberation recommended the following 1. The inclusion criteria should be revised to include screening of the subjects for COVID-19 by RT-PCR method. 2. The SpO2/FiO2 parameter should be omitted in inclusion criteria 3. The primary objective should be assessment of safety. 4. The secondary outcomes should include, progression of disease by WHO ordinal scale, RT-PCR negativity and mortality rate. 5. Intradermal sensitivity testing should be carried out in the patients before

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			infusion. Accordingly, firm should submit revised protocol for consideration of CDSCO.
5.	BIO/CT/20/000158 SARS-CoV-2 (Covid-19) Vaccine (RBD of SARS-CoV-2)	M/s Biological E Ltd., Hyderabad	Firm presented Phase I/II clinical trial protocol before the committee along with non-clinical toxicity data. The committee after detailed deliberation recommended following: 1. Complete Non-clinical toxicity data on rabbits should be submitted. 2. Firm should carry out ascending dose safety study starting with 15mcg dose, 25 mcg dose & 50mcg dose before proceeding to Phase II study. 3. Animal challenge studies should be carried out parallely. Accordingly, firm should submit the revised protocol along with the animal toxicity data.
6.	BIO/CT/20/000159 Whole Virion, Inactivated Corona Virus Vaccine (BBV152)	M/s Bharat Biotech Ltd., Hyderabad	Firm presented Phase III clinical trial protocol along with interim data of Phase I & II clinical trial. The committee noted the interim data of Phase I & II clinical trial. After detailed deliberation the committee opined that the design of the Phase III study is in principle satisfactory except for clarification on definition of asymptomatic, etc. However, the study should be initiated with appropriate dose identified from the Phase II safety & immunogenicity data. Accordingly, the firm should submit safety & immunogenicity data from Phase II trial for consideration.
7.	F. NO. BIO/CT/20/000154 Mycobactrium w (immunomodulator)	M/s Cadila Pharmaceuticals Ltd., Ahmadabad	The firm presented their proposal before the committee. After detailed deliberation the committee re commended for grant of permission to conduct Phase III Clinical Trial subject to the condition 1. In the inclusion criteria radiographic infiltrates by imaging (chest, x-ray, CT Scan etc" should be deleted 2. SpO2 ≤ 94% on room air should be revised to mention as "SpO2 ≤ 90%". Accordingly firm should revise the protocol and submit to CDSCO.

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8.	F. NO. BIO/CT/20/000162 Gam COVID Vac Combined vector vaccine	M/s Dr Reddys Laboratories Limited	Firm presented Phase III clinical trial protocol before the committee along with overseas Phase I/II clinical trial & non-clinical toxicity data before the committee. The committee noted that the safety & immunogenicity data in overseas Phase I/II studies is small and there is no data available on Indian subjects. After detailed deliberation the committee recommended that the firm should follow the regulatory requirements and conduct Phase II/III clinical trial in the country with proper monitoring for humoral & cell mediated immune response. Accordingly, firm should submit the protocol for consideration of the committee. Further, firm shall submit the stability data as per usage conditions.