Recommendations of the SEC meeting to examine COVID-19 related proposals under accelerated approval process made in its 135th meeting held on 02.01.2021 CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/20/000194 Novel Corona Virus 2019-nCoV vaccine	M/s Cadila Healthcare Limited, Ahmedabad	The firm presented interim safety and immunogenicity data of ongoing Phase I/II clinical trial of Novel Corona Virus 2019-nCoV vaccine along with proposed phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of proposed phase III clinical trial protocol subject to the condition that the vaccine efficacy should be assessed on the data generated after day 84 from the first dose.
2.	BIO/MA/20/000103 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) (EUA)	M/s Bharat Biotech International limited, Hyderabad	In light of the recommendations of the committee dated 01.01.2021, the firm further presented the updated data, justification and requested for consideration of their proposal in the wake of incidence of new mutated corona virus infection. As already noted by the committee, this vaccine is Inactivated Whole Virion, Corona Virus Vaccine having potential to target mutated corona virus strains. The data generated so far demonstrates a strong immune response (both antibody as well as T cell) and in-vitro viral neutralization. The ongoing clinical trial is a large trial on 25800 Indian subjects in which already 22500 subjects have been enrolled including subjects with comorbid conditions as well which has demonstrated safety till date. Moreover, firm has presented the safety and efficacy data from Non-human primate challenge study where the vaccine has been found to be safe and effective. In view of above, after detailed deliberation, the committee recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains. Further, the firm shall continue the on-going Phase III clinical trial and submit data emerging from the trial as and when available.