

**Recommendations of the SEC meeting to examine COVID-19 related proposals under accelerated approval process made in its 137<sup>th</sup> meeting held on 12.01.2021 CDSCO, HQ New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	BIO/MA/20/000103  Whole Virion Inactivated Corona Virus Vaccine (BBV152)	M/s Bharat Biotech International limited, Hyderabad	<p>In continuation of meeting dated 11.01.2021, Firm presented updated protocol for rolling out the Whole Virion Inactivated Corona Virus Vaccine (BBV152), for restricted use in emergency situation in clinical trial mode, factsheet, informed consent form and adverse event form.</p> <p>The committee suggested certain changes in above documents which were incorporated and final versions were presented before the committee.</p> <p>The firm has already taken approval of the ICMR Central Ethics Committee on Human Research (CECHR) for the Implementation Plan – “Restricted use of COVAXIN under clinical trial mode” on 11.01.2021.</p> <p>After detailed deliberation, the committee recommended for approval of the protocol for rolling out the Whole Virion Inactivated Corona Virus Vaccine (BBV152) in clinical trial mode along with factsheet, informed consent form and adverse event form.</p>