21 June 2021

IP BIOTECH, INC.

Emergency Use Authorization (EUA) for Whole Virion, Inactivated Corona Virus Vaccine [Covaxin]

This applies to the request for approval of the submitted equivalent Good Manufacturing Practice (GMP) Certificate, Risk Management Plan and updated Chemistry, Manufacturing and Controls (CMC) as conditions prior to the commercial importation of the Whole Virion, Inactivated Corona Virus Vaccine [Covaxin] ("Bharat Biotech COVID-19 Vaccine").

Finding the compliance to be substantial, the Food and Drug Administration (FDA) hereby revises the EUA to remove the above stated conditions prior to the commercial importation of the Bharat Biotech COVID-19 Vaccine.

The foregoing revision is made pursuant to the discretionary power of the FDA under Section 6 of Executive Order (EO) No. 121, entitled *"Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization for COVID-19 Drugs and Vaccines, Prescribing Conditions Therefor, and for Other Purposes,"* to revisit any issued EUA as may be appropriate to protect the general public health and safety.

The details of the Bharat Biotech COVID-19 Vaccine are as follows:

Product Name:	COVAXIN™ (Whole Virion Inactivated Corona Virus Vaccine)
Dosage Strength and Form:	Sterile white translucent liquid for injection, containing 6mcg of Whole-virion, Inactivated Corona Virus Antigen (strain NIV-2020-770)
Pharmacologic category:	Vaccine
Storage:	Store at +2 to +8 ^{0}C. Do not freeze. Shake well before use. Protect from light. Once opened, should be used within 6 hours
Packaging:	5 ml multi- dose vials (10 doses of 0.5 ml each)
Manufacturer:	Bharat Biotech International Limited, Genome Valley, Turkapally, Shamirpet Mandal, Medchal-

	Malkajgiri District- 500 078, Telangana State, India
Indication:	For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older

After careful consideration of the application, with all its supporting documents and a review of local experts, the FDA hereby grants approval for the emergency use of Bharat Biotech COVID-19.

Under Executive Order (EO) No. 121, s. 2020 entitled *"Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization for COVID-19 Drugs and Vaccines, Prescribing Conditions Therefore, and for Other Purposes,"* an EUA on a COVID-19 vaccine shall be issued and remain validity only when all of the following circumstances are present:

1. Based on the totality of evidence available to date, including data from adequate and well- known controlled trials, it is reasonable to believe that the Bharat Biotech COVID-19 Vaccine may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the Bharat Biotech COVID-19 Vaccine, when used to diagnose, prevent, treat COVID-19, outweigh the known and potential risks of said Vaccine as of date; and
3. There is currently no adequate, approved and available alternative to the product for diagnosing, preventing or treating COVID-19.

In issuing this EUA, consideration has been given to the emergency use authorizations given by counterpart National Regulatory Authorities (NRAs) such as India and Mexico. This was followed by a rigorous and thorough review of all submitted published and unpublished clinical trial data and product information.

This EUA is not a marketing authorization or a Certificate of Product Registration (CPR). Hence, this EUA cannot be used as an authorization to market the vaccine commercially.

While the evaluation process was facilitated, strict conditions on the authorization granted in this Letter shall be imposed as follows

I. Scope

The scope of the EUA shall be limited as follows:

A. IP Biotech, Inc. shall supply Bharat Biotech COVID-19 Vaccine only to emergency response stakeholders consistent with the terms and conditions of this EUA.

"Emergency response stakeholders" shall refer to the Department of Health (DOH) or the National Task Force Against COVID-19 (NTF) or their designees authorized to procure or purchase Bharat Biotech COVID-19 Vaccine in line with the COVID-19 vaccination program. Designees may include hospitals (public

and private), health facilities of other National Government Agencies, Local Government Units (LGUs) and other members of the Private Sector.

B. The Bharat Biotech COVID-19 Vaccine shall be administered only by vaccination providers, and used only to prevent COVID-19 in individuals ages 18 and older.

"Vaccination providers" shall refer to the facility, organization, or a healthcare provider, including non-physician healthcare providers such as nurses or pharmacists, authorized by the DOH or the NTF to administer the Bharat Biotech COVID-19 Vaccine in accordance with the COVID-19 vaccination program.

II. Dosage Strength and Form

Bharat Biotech COVID-19 Vaccine should be supplied as sterile liquid injection in 5 ml multi-dose vial (10 doses). It is presented in USP type 1 glass vial. The dosing regimen is two doses of 0.5 ml each. It should be administered on Day 0 and Day 28 respectively, as intramuscular injection. Bharat Biotech COVID-19 Vaccine is a white translucent liquid free from particulate matter containing 6 mcg of Whole - virion, Inactivated Corona Virus Antigen (strain NIV-2020-770).

III. Cold Chain Management

In the absence of agreement with the DOH or NTF, IP Biotech, Inc. shall provide appropriate cold chain requirements for storage, transport and handling until it is delivered to the inoculation sites, and ensure that a contingency plan is in place.

IP Biotech, Inc. shall have a system of monitoring to ensure traceability and that the vaccine is consistent with the storage requirements from the manufacture and transport to the inoculation sites.

IP Biotech, Inc. shall observe strict compliance with the standards for Good Distribution Practices (GDP) and Good Storage Practices (GSP) adopted pursuant to Administrative Order No. 2013-0027 including supplements thereto (i.e. WHO Technical Report Series No. 961, 2011, Annex 9 and Technical Report Series No. 992, 2015, Annex 5). IP Biotech, Inc. shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

IV. Pharmacovigilance

IP Biotech, Inc. shall have a comprehensive pharmacovigilance system for Bharat Biotech COVID-19 Vaccine following system or protocol for a registered drug and biologic product as stated in the FDA Circular No. 2020-003. Submission of serious and non-serious adverse reaction reports is mandatory.

V. Responsibility of Emergency Response Stakeholders and Vaccination Providers

Under FDA Circular No. 2020-036 or the *Guidelines for the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19,* the pharmacovigilance obligations

and post-authorization commitments imposed in the Letter shall be shared to the fullest extent possible and applicable by the national procurer and health program implementors, and their designees. Emergency response stakeholders and vaccination providers shall have the following responsibilities.

A. Emergency response stakeholders shall:

1. Identify inoculation sites to receive the Bharat Biotech COVID-19 Vaccine, and ensure appropriate storage and cold chain management is maintained in said sites, in the absence of an agreement with IP Biotech, Inc.;
2. Ensure administration of the Bharat Biotech COVID-19 is consistent with the terms of this Letter, latest product information and the COVID-19 Vaccination Program; and
3. Ensure that vaccination providers of the procured Bharat Biotech COVID-19 Vaccine are aware of this Letter of Authorization and the terms herein and any subsequent amendments thereof, instructed about the means which they are to obtain and administer the Bharat Biotech COVID-19, and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

1. Administer the Bharat Biotech COVID-19 Vaccine, in accordance with this EUA, and participate and comply with the terms and training required by the DOH for the COVID-19 Vaccination Program;
2. Provide fact sheets to the recipients and caregivers, and provide necessary information for receiving their second dose;
3. Obtain written informed consent from the recipient of the Bharat Biotech COVID-19 Vaccine prior to vaccination;
4. Report any Adverse Events Following Immunization on the use of Bharat Biotech COVID-19 Vaccine;
5. Monitor and comply with vaccine management requirements (e.g. obtaining, tracking and handling vaccine) of the DOH; and
6. Ensure that records associated with this EUA are maintained until notified by FDA. Such records shall be made available to DOH and FDA for inspection upon request.

Notwithstanding the foregoing, IP Biotech, Inc. has the ultimate responsibility for monitoring the safety and quality of the Bharat Biotech COVID-19 Vaccine.

VI. Validity

Unless otherwise revoked, this EUA shall be valid only within the duration of the declared public health emergency due to COVID-19, or upon issuance of a marketing authorization/Certificate of Product Registration.

In the event that the declared public health emergency is lifted, or when a COVID-19 drug or vaccine is registered with the FDA, this EUA shall have a provisional validity

for a period of one (1) year from date of lifting of the declaration or registration of the drug or vaccine for the sole purpose of exhausting remaining products.

This EUA is subject to revocation, suspension or cancellation due to violations of pharmacovigilance obligations and post authorization commitments, as well as any violation of the EO No. 121, and RA 3720 as amended by RA No. 9711, FDA Circular No. 2020-036, and other rules and regulations issued thereunder.

For strict compliance.