Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

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Second Amendment to the Emergency Use Authorization (EUA) for SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], Sinovac Life Sciences Co., Ltd

This refers to the request for an amendment of the Emergency Use Authorization (EUA) for the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], Sinovac Life Sciences Co., Ltd to expand the authorized indication to pediatric age groups.[1]

After due consideration, and a review of experts, the Food and Drug Administration (FDA) hereby revises the EUA granted to the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] to reflect the requested change.

The foregoing revisions are 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] are as follows:

Product Name:	SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac]
Dosage Strength and Form:	600 SU/0.5 mL Suspension for Injection (IM) One-dose vial; 1200 SU/mL (600 SU/0.5 mL) Two-dose vial
Pharmacologic category:	Vaccine
Storage:	Store at 2° to 8°C. Protect from light. Do not freeze.
Shelf-life:	One dose vial -12 months; Two-dose vial - 6 months
Packaging:	Vial (Box of 40's)

[1] We refer you to the EUA dated 22 February 2021 and Amended EUA dated 15 November 2021

Manufacturer:	Sinovac Life Sciences Co., Ltd.
Indication:	This product is suitable for clinically healthy people aged 6 years old and above susceptible to virus.

After careful consideration of the application, with all its supporting documents and a review of local experts, the FDA has been satisfied that all the conditions for the issuance of an EUA exist as provided 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 Therefor, and for Other Purposes,"* particularly:

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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], when used to diagnose, prevent, or 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 China, Brazil, Indonesia and WHO- Emergency Use Listing (EUL). 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.

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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] shall be administered only by vaccination providers, and used only to prevent COVID-19 in clinically healthy individuals ages 6 years old and above.

"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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] in accordance with the COVID-19 vaccination program.

II. Dosage Strength, Form and Administration

SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] should be supplied as an opalescent aqueous suspension in single dose vials. Each vial must contain 0.5ml per dose containing 600SU of indicated SARS-CoV-2 inactivated virus as antigen. The second dose should be given after four weeks (4) from the first dose.

A third dose at least 6 months after completion of the primary course of 2 doses of the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] may be administered in the following populations:

1. Healthcare professionals and workers 18 years of age or older with frequent institutional or occupational exposure to SARS-CoV-2;
2. Individuals who may fail to mount an adequate response to a primary series of vaccines such as senior citizens and patients 18 years of age or older who are diagnosed with immunocompromised conditions; and
3. Persons 18 through 60 years of age with comorbidities and at high risk of developing severe COVID-19.

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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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.

IP Biotech, Inc. shall ensure compliance with the SARS-CoV-2 Vaccine (Vero Cell), Inactivated Risk Management Plan (RMP) along with the Philippine-specific Annex. Additional pharmacovigilance activities such as interventional and non-interventional studies (ongoing or new studies, or additional activities) shall be implemented as stated in the RMP. The RMP must be updated whenever there is a significant change which may affect the benefit-risk profile of the vaccine or when an important milestone is reached.

IP Biotech, Inc. shall submit summary safety reports every 6 months or as required by the FDA.

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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

    1. Administer the SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac], 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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac] prior to vaccination;
4. Report any Adverse Events Following Immunization on the use of SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac];
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 SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac].

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.