Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

14 February 2023

**ZUELLIG PHARMA CORPORATION**
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**Eighth Amendment to the Emergency Use Authorization (EUA) for COVID-19 mRNA Vaccine (Nucleoside Modified) Dispersion for Injection [SPIKEVAX][1]**

This refers to the request to amend the Emergency Use Authorization (EUA) of the COVID-19 mRNA Vaccine (Nucleoside Modified) Dispersion for Injection [SPIKEVAX] (COVID-19 Vaccine Moderna) to include booster doses for individuals 12 to 17 years old.

After due consideration, the Food and Drug Administration (FDA) updates the EUA of the COVID-19 Vaccine Moderna to reflect the requested amendment.

The foregoing change 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.

Accordingly, the Food and Drug Administration (FDA) hereby revises the EUA granted to COVID-19 Vaccine Moderna.

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

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| **Product Name:** | COVID-19 mRNA-1273 (Nucleoside Modified) [SPIKEVAX] |
| **Dosage Strength and Form:** | 100 mcg dispersion for injection |
| **Pharmacologic category:** | Vaccine |
| **Storage and Shelf Life:** | Unopened vial. Store frozen between -25ºC to -15ºC for 9 months. Once thawed, the unopened vaccine may be stored at 2º to 8º C, protected from |

[1] We refer you to the EUA dated 5 May 2021, Amended EUA dated 26 August 2021, Second Amendment to the EUA dated 02 September 2021, Third Amendment to the EUA dated 09 December 2021, Fourth Amendment to the EUA dated 28 December 2021, Fifth Amendment to the EUA dated 24

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| | light for a maximum of 30 days. Within this period, up to 12 hours may be used for transportation. The unopened vaccine may be stored at 8º to 25º C up to 24 hours after removal from refrigerated conditions. Vials should not be refrozen.<br>Shelf life of 9 months.<br><br>Shelf life of 9 months for drug substance CX-024414 at 15ºC to -25ºC, and 12 months for mRNA-127 3 LNP at 60ºC to -90ºC. Changes to the approved annual stability protocol of active substance CX-024414 and mRNA-127 3 LNP to harmonise stability protocol across all manufacturing sites are noted. |
| **Packaging:** | Multidose vial which contains 10 doses of 0.5 mL per dose or a maximum of 20 doses of 0.25 mL each. |
| **Manufacturer:** | Moderna Biotech Spain S.L., Calle del Principe De Vergara 132 Plt 12, Madrid 28002, Spain |
| **Indication:** | For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 6 years of age and older |

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 COVID-19 Vaccine Moderna may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the COVID-19 Vaccine Moderna, 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, recognition and reliance have been accorded to the Emergency Use Listing (EUL) of the World Health Organization (WHO), and emergency use authorizations given by mature and established National Regulatory Authorities (NRAs) such as the European Medicines Agency and the United States of America. Under Section 5 of EO No. 121, the Director General of the FDA has been granted power to implement reliance and recognition processes, and accept regulatory decisions of recognized and established regulatory authorities.

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. Zuellig Pharma Corporation shall supply COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna shall be administered only by vaccination providers, and used only to prevent COVID-19 in individuals ages 12 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 COVID-19 Vaccine Moderna in accordance with the COVID-19 vaccination program.

## II. Dosage Strength, Form and Administration

COVID-19 Vaccine Moderna should be supplied as a white to off white frozen suspension for injection in multidose vials. Each vial contains 100 mcg of nucleosidemodified messenger RNA. The multidose vial contains 10 doses of 0.5mL (100micrograms) per dose or maximum of 20 doses of 0.25ml (50 micrograms) per dose.

- For individuals ages 12 years old and above, 0.5 ml of Spikevax is administered as a 2-dose regimen. The second dose should be administered 28 days after the first dose intramuscularly.
- For individuals aged 6 to 11 years old, 0.25 ml of Spikevax is administered as a 2-dose regimen. The second dose should be administered 28 days after the first dose intramuscularly.
- For the severely immunocompromised aged 12 years and older, a third dose (0.5 mL, 100 micrograms) may be given at least 28 days after the second dose.

A booster dose (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) of the COVID-19 Vaccine Moderna may be administered intramuscularly at least 4 to 6 months after the second dose in individuals 12 years of age and older. The decision when and for whom to implement a third dose of the COVID-19 Vaccine Moderna should be made based on available vaccine effectiveness

data, taking into account limited safety data.

## III. Cold Chain Management

In the absence of agreement with the DOH or NTF, Zuellig Pharma Corporation 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.

Zuellig Pharma Corporation 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.

Zuellig Pharma Corporation 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). Zuellig Pharma Corporation shall allow FDA Inspectors to conduct inspection of the cold storage sites including the transport vehicles.

## IV. Pharmacovigilance

Zuellig Pharma Corporation shall have a comprehensive pharmacovigilance system for COVID-19 Vaccine Moderna 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.

Zuellig Pharma Corporation shall ensure compliance with the 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.

Zuellig Pharma Corporation shall submit monthly summary safety reports as planned and discussed in the RMP.

## 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 COVID-19 Vaccine Moderna, and ensure appropriate storage and cold chain management is

maintained in said sites, in the absence of an agreement with Zuellig Pharma Corporation;
2. Ensure administration of the COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna, and provided with approved fact sheets.

B. On the other hand, vaccination providers shall:

1. Administer the COVID-19 Vaccine Moderna, 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 COVID-19 Vaccine Moderna prior to vaccination;
4. Report any Adverse Events Following Immunization on the use of COVID19 Vaccine Moderna;
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, Zuellig Pharma Corporation has the ultimate responsibility for monitoring the safety and quality of the COVID-19 Vaccine Moderna.

## 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.