

IND Number 27073
Sequence No. 0007

December 7, 2020

Marion Gruber, PhD
Director, Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

**Submission Type: Response to multiple comments, Financial Disclosure Certification,
Carton/Container Labeling**

Dear Dr. Gruber:

Reference is made to pre-assigned submission tracking number (STN) EUA 27073 for Emergency Use Authorization of the new drug mRNA-1273.

The purpose of this submission is to support the Emergency Use Authorization Request submitted on 30 November 2020 for mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2).

Please note, in the November 30, 2020, submission of the EUA application to FDA, Moderna requested to change the frozen storage statement in the draft provider fact sheet and full prescribing information to remove the phrase “until ready for use” to avoid confusing providers on when to remove the vaccine from frozen storage for refrigerated storage or thawing. Moderna acknowledged that this phrase currently appears on the vial label and carton and proposed to also remove it from those components for the next printing. In the Division’s December, 1, 2020, labeling comments on the draft provider fact sheet, this change was accepted, and the revised artwork was requested to be submitted to the EUA application. The revised artwork with this text removed is provided in this submission for the following:

- 702210 mRNA-1273 EUA Vial Label
- 702208 mRNA-1273 EUA Carton – Manual
- 702209 mRNA-1273 EUA Carton – Automated

Additionally, Moderna is preparing for the use of an additional packaging line at Catalent, the contract packaging facility. Use of the new line requires a separate set of labeling with specific artwork control numbers, 2D barcodes for component identification, and a black color box on the back of the carton for laser coding the variable information on the back panel. The product content on this alternate set of artwork is identical to the components listed above. Included in this submission is this alternate set of artwork for the following:

- 702195 mRNA-1273 EUA Vial Label – New Line
- 702196 mRNA-1273 EUA Carton – New Line

In total, this submission includes:

1.2 Cover Letter

1.3.4 Form 3454 – Associated with EUA IR #2

1.11.3 Response to Comments regarding Vaccine Efficacy After First Dose – EUA IR #7 Q's 4 and 5

1.11.3 Response to CBER Communication Regarding Clinical Topics – EUA IR #8

1.14.1.1 Draft Emergency Packaging Carton – New Line

1.14.1.1 Draft Emergency Packaging Carton

1.14.1.1 Draft Emergency Packaging Label

1.14.1.1 Draft Emergency Packaging Label – New Line

5.3.5.1 mRNA-1273-P201: Three MedWatch forms - Associated with EUA IR #8

5.3.5.1 mRNA-1273-P301: SAE Listing – EUA IR #8

If FDA has any questions, please do not hesitate to contact me directly at (b) (6) or at (b) (6)@modernatx.com.

This eCTD submission has been prepared by PPD Development, Inc. in full compliance with ICH and FDA guidance. The eCTD has been verified and confirmed to be virus and spyware free. PPD utilizes Palo Alto Traps v4.2.2. All technical questions should be directed to (b) (6) at PPD (b) (6) or email at (b) (6)

Yours Sincerely,

Carla
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Digitally signed
by Carla Vinals
Date: 2020.12.07
19:44:20 -05'00'

Carlota Vinals
VP, Regulatory Affairs Strategy
ModernaTX, Inc.
200 Technology Square
Cambridge, MA 02139
Tel.: (b) (6) Fax: (b) (6)

Email: (b) (6)@modernatx.com