

IND Number 27073
Sequence No. 0022

December 18, 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 Labeling Comments

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).

This submission includes:

1.2 Cover Letter

1.14.1.3 Draft Fact Sheet for Recipients and Caregivers – Clean (version 4.0, December 18, 2020)

1.14.1.3 Draft Fact Sheet for Recipients and Caregivers – Redline (version 4.0, December 18, 2020)

1.14.1.3 Draft EUA Fact Sheet for Healthcare Providers and Full EUA Prescribing Information – Clean (version 4.0, December 18, 2020)

1.14.1.3 Draft EUA Fact Sheet for Healthcare Providers and Full EUA Prescribing Information – Redline (version 4.0, December 18, 2020)

The above documents are provided in both Word and PDF format and replace the Draft Fact Sheets provided in Sequence 0021 (December 18, 2020).

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
Vinals

Digitally signed
by Carla Vinals
Date: 2020.12.18
20:42:05 -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