

IND Number 27073
Sequence No. 0021

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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
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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).

Information concerning mRNA-1273 Drug Product Lot 6008620003 (Catalent Lot 027L20) is being provided. This lot is subject of a deviation as the result of a leak prior to the filling operation. Per a teleconference on December 16, 2020 with FDA (John Eltermann, Robin Levis, Robert Sausville and Jerry Weir), the CofA for Lot 6008620003 (Catalent Lot 027L20), the deviation investigation from Catalent (REC 284379), and the technical summary are being provided. The CofA is being submitted in Section 3.2.P.5.4 as an attachment to that section. At the request of FDA, this Quality Information Amendment is being simultaneously submitted to IND 19745 and EUA 27073.

This submission includes:

1.2 Cover Letter

1.11.1 Quality Information Amendment

1.11.1 Attachment

1.14.1.3 Draft Fact Sheet for Recipients and Caregivers – Clean (12.17.20, v3.0)

1.14.1.3 Draft Fact Sheet for Recipients and Caregivers – Redline (12.17.20, v3.0)

1.14.1.3 Draft EUA Fact Sheet for Healthcare Providers and Full EUA Prescribing Information – Clean (12.17.20, v3.0)

1.14.1.3 Draft EUA Fact Sheet for Healthcare Providers and Full EUA Prescribing Information – Redline (12.17.20, v3.0)

3.2.P.5.4 Section 3.2.P.5.4 mRNA-1273 Drug Product Certificate of Analysis Lot# 6008620003

The above documents are provided in both Word and PDF format.

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
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