

BLA Number 125752
Sequence No. 0035

December 14, 2021

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: Artwork and Package Insert Comments Received on Dec 10, 2021 (IR #33)

Dear Dr. Gruber:

Reference is made to BLA 125752 for the initial Biologics License Application (BLA) for mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2) currently under review with the agency.

The purpose of this submission is to submit revised packaging artwork and package insert as requested in the comments provided on December 10 (IR#33).

- Artwork for the vial labels and cartons has been revised to change the statement “No preservative” to “Contains no preservative”, as requested. Additionally, on the bottom of the cartons, the following statement has been added, “Patent(s): www.modernatx.com/patents”.
- Revisions to the package insert have been accepted and responses to CBER’s comments have been provided in the redlined version of the package insert. A clean version has also been provided.

If FDA has any questions, please do not hesitate to contact me directly at (617) 417-4428 or at michelle.olsen@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,

Michelle
Olsen

Digitally signed by
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