

BLA Number 125752
Sequence No. 0034

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: Response to FDA Comments on Information Request #31 received on
10 December 2021**

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 respond to information request #31, FDA's comments on post marketing requirement/commitment (PMR/PMC) studies.

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
Michelle Olsen
Date: 2021.12.14
08:30:40 -05'00'

Michelle Olsen
Associate Director, Regulatory Affairs Strategy
ModernaTX, Inc.
200 Technology Square
Cambridge, MA 02139
Tel.: (617) 417-4428; Fax: (b) (6)
Email: michelle.olsen@modernatx.com