

BLA Number 125752
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October 08, 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
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**Submission Type: Responses to CMC Information Requests received on September 23, 2021 (IR# 3) and September 28, 2021 (IR# 6)
Response to Clinical Information Request received on September 24, 2021 (IR# 5 Group# 1)
BLA CBER Requested Tables**

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 responses to CMC Information Requests received on September 23, 2021 (IR# 3) and September 28, 2021 (IR# 6). A response to a clinical information request received on September 24, 2021 (IR# 5 Group# 1, with associated tables) as well as the final batch of the BLA CBER Requested Tables is also included. Please note, in the CBER Requested Tables, Table 22 has been slightly updated compared to what was submitted previously, with adverse reactions within 30 minutes of vaccination rather than unsolicited AEs (to match other subgroup tables).

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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