

BLA Number 125752
Sequence No. 0010

October 06, 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
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Silver Spring, MD 20993-0002

Submission Type: Response to Information Request received on September 28, 2021
Clinical – mRNA-1273-P301 CRFs and linked 16.3.1

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 a response the efficacy data request for IR# 6 received on September 28, 2021. Also, it was observed that a number of CRFs included in the Initial BLA (Seq 0003, August 24, 2021) for the mRNA-1273-P301 CSR were placeholder documents and we are now submitting the CRFs along with a fully linked Section 16.3.1.

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

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