

BLA Number 125752
Sequence No. 0051

January 27, 2022

Peter Marks, MD PhD
Director, Center for Biologics Evaluation and Research
Acting Director, Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
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Submission Type: Labelling – PI
Response to Information Request received on January 26, 2022 (IR #48)

Dear Dr. Marks:

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 to an Information Request received on January 26, 2022 (IR# 48) and an updated PI with corresponding changes with regards to IR#48 and editorial changes requested by the Agency on January 27, 2022 (via phone).

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) @ppd.com.

Yours Sincerely,

Michelle Olsen
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Michelle Olsen
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