

**BLA Number 125752**  
**Sequence No. 0024**

November 19, 2021

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**Submission Type: Responses to CMC Information Requests received on October 14, 2021 (IR# 9)  
and November 01, 2021 (IR#13)  
Responses to Clinical IR#20 and Labelling IR#21**

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 October 14, 2021 (IR# 9) and November 01, 2021 (IR#13) regarding CMC: TOR and CPD limits and DP Stability program. Also included in this submission are responses to the Clinical Information Request received on November 12, 2021 (IR#20) and the Labelling Information Request received on November 15, 2021 (IR#21).

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