

**BLA Number 125752**  
**Sequence No. 0029**

December 03, 2021

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Document Control Center  
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**Submission Type: Responses to CMC Information Requests received on November 30, 2021 (IR#25)**

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 November 30, 2021 (IR#25) regarding CMC: batch analysis data, hold times, analytical test laboratories, stability data and reprocessing steps.

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)

Sincerely,

**Michelle  
Olsen**

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