

BLA Number 125752
Sequence No. 0019

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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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**Submission Type: Responses to CMC Information Requests received on October 20, 2021 (IR# 10)
PASS protocols requested in IR#14**

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 20, 2021 (IR# 10) regarding CMC: plasmid manufacturing. Additionally, included in this submission are protocols for P902, P903, P904, and P905, as requested in IR#14.

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 Michelle Olsen
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