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BLA Number 125752
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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
WO71, G112
Silver Spring, MD 20993-0002

Submission Type: **BLA 125752 60 Day Submission for Module 3**

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 provide the Moderna deliverables for Module 3 as discussed in an email communication dated September 24, 2021 concerning the submission for the following items to STN 125752**:**

- (b) (4) PPQ Lonza (USPO-29627 protocol submitted in BLA 125752 SN002, executed PPQ data to be provided on October 15, 2021)
- (b) (4) Mixers PPQ (PV-VAL-PRO-0056 protocol submitted in BLA 125752 SN002, executed PPQ data to be provided on October 15, 2021)
- (b) (4) protocol submitted in BLA 125752 SN002, executed PPQ data to be provided on October 15, 2021)
- LSS Change (PV-VAL-PRO-0052 protocol submitted in BLA 125752 SN002, executed PPQ data to be provided on October 15, 2021)
- (b) (4) (PV-VAL-PRO-0015 and PV-VAL-PRO-0016 protocols submitted in BLA 125752 SN002, executed PPQ data to be provided on October 15, 2021)
- Direct Injection Purity and Product-related Impurity Analytical Method (QC-MVP-0025 method validation submitted in BLA 125752 SN002, final executed analytical bridging data to be submitted on October 10, 2021 per RTQ received September 22, 2021)
- (b) (4) (Stability protocols provided in Section 3.2.S.7.1 {CX-024414} or Section 3.2.S.7.1 {mRNA-1273 LNP} in BLA 125752 SN002 and executed stability data to be provided on October 15, 2021)
- Catalent Vial Line (b) (4) PPQ for 6.3 mL Fill (VPPQ-256-100-00010-P-ADD01 protocol submitted in BLA 125752 SN002, executed PPQ data to be provided on October 15, 2021)

As clarified in the Response to Information Request #3 received 23 September 2021 (BLA 125752 SN 011 dated October 08, 2021), as well as in this submission, the intent is to continue testing the purity of the

mRNA-1273 Drug Product, CX-024414 mRNA and mRNA-1273 LNP in accordance with SOP-0996 until the BLA is approved. Once the BLA is approved, the transition of the purity testing of the mRNA-1273 Drug Product, CX-024414 mRNA and mRNA-1273 LNP from SOP-0996 to SOP-1142 will independently occur within 60 days for the initiation of manufacturing. The Sponsor will provide a formal notification to the BLA when the transition has been completed concerning lot impact.

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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