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BLA Number 125752
Sequence No. 0025

November 22, 2021

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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Silver Spring, MD 20993-0002

Submission Type: Responses to Comments on Post Marketing Studies Dated 19 Nov 2021 (IR#22)
Quality Information Amendment – Norwood Manufacturing Facility Response to discussion on 29 October 2021.

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 respond to Information Request #22 on post-marketing studies, received 19Nov2021.

Also included in this submission is a copy of Moderna's responses to comments obtained on 29 October 2021 during an on-site pre-licensure inspection of Moderna's Norwood Manufacturing facility. This response document contains self-defined implementation dates for various tasks, that will be tracked in our quality system. Any documents related to the content in this response will be available upon request and also available to review at the next inspection.

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

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