moderna

200 Technology Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-649-3744

BLA Number 125752
Sequence No. 0021

November 09, 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
WO71, G112
Silver Spring, MD 20993-0002

Submission Type: Real World Effectiveness Study Protocol (P901) for Information Request #16
Response to Information Request #15 regarding Clinical

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 protocol version 3.0 associated with study mRNA-1273-P901 in response to Information Request #16. Also included in this submission are clinical responses to Information Request #15 and requested source tables.

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
Date: 2021.11.09 10:55:58 -05'00'

Michelle Olsen
Associate Director, Regulatory Affairs Strategy
ModernaTX, Inc.
200 Technology Square
Cambridge, MA 02139
Tel.: (617) 417-4428; Fax: (b) (6)
Email: michelle.olsen@modernatx.com