

IND Number 27073
Sequence No. 0006

December 7, 2020

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: mRNA-1273-P301 Case Report Forms, Safety Tables, and Listings for the mRNA-1273-P301 study based on the data snapshot from 25 Nov 2020, List of Investigator Sites for mRNA-1273-P201 and mRNA-1273-P301, Executive Summary of Clinical Safety, and a list of VRBPAC Meeting attendees.

Dear Dr. Gruber:

Reference is made to pre-assigned submission tracking number (STN) EUA 27073 for Emergency Use Authorization of the new drug mRNA-1273.

The purpose of this submission is to support the Emergency Use Authorization Request submitted on 30 November 2020 for mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2).

This submission includes:

1.2 Cover Letter

1.6.2 List of VRBPAC Meeting Attendees

1.11.3 CBER Requested Tables mRNA1273-P301 - from the 25 Nov 2020 Data Snapshot

1.11.3 Executive Summary of Clinical Safety mRNA1273-P301 - from the 25 Nov 2020 Data Snapshot

5.3.5.1 mRNA-1273-P201:

List of Investigators mRNA-1273-P201

5.3.5.1 mRNA-1273-P301:

Case Report Forms (all SAEs)

List of Investigators mRNA-1273-P301

Unblinded Moderna P301 Safety Listings Batch 1 from the 25 Nov 2020 Data Snapshot

Unblinded Moderna P301 Safety Tables Batch 1 from the 25 Nov 2020 Data Snapshot

Unblinded Moderna P301 Safety Listings Batch 2 from the 25 Nov 2020 Data Snapshot

Unblinded Moderna P301 Safety Tables Batch 2 from the 25 Nov 2020 Data Snapshot

If FDA has any questions, please do not hesitate to contact me directly at (b) (6) or at (b) (6)@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) PPD (b) (6) or email at (b) (6)

Yours Sincerely,

Carla Vinals
Digitally signed
by Carla Vinals
Date: 2020.12.07
15:57:44 -05'00'

Carlota Vinals
VP, Regulatory Affairs Strategy
ModernaTX, Inc.
200 Technology Square
Cambridge, MA 02139
Tel.: (b) (6); Fax: (b) (6)
Email: (b) (6)@modernatx.com