

IND Number 27073
Sequence No. 0011

December 10, 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: Response to multiple comments

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

1.11.3 Response to Comments – IR 11 – Items 1 – 5

1.11.3 Response to Comments – IR 11 – Item 6

1.11.3 Response to Comments – IR 13 – Items 1 thru 3 – 09Dec

1.11.3 Response to Comments – Addendum to inspection finding response – 08Dec2020

1.11.3 Moderna Submission Plan Supporting EUA_Version 9_09Dec

1.14.1.3 Draft EUA Fact Sheet – providers (clean and redline)

1.14.1.3 Draft EUA Fact Sheet – recipients and caregivers (clean and redline)

1.14.1.3 Draft EUA Prescribing Information (PI) (AR Tables Sections 11-21) – Clean and Redline – word version

5.3.5.1 mRNA-1273-P301:

Additional Death Narratives – FDA Request IR 11 – Subject US3492243

Additional Death Narratives – FDA Request IR 11 – 08 December 2020

Additional Death Narratives – FDA Request IR 11 - SubjectUS3212326

Safety Events Listing 12Nov2020 through 25Nov2020 on 08Dec2020

mRNA-1273-P301_FDA Request #11_Narratives Bell's Palsy

adhoc P301 tables for IR 13

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) at PPD (b) (6) or email at (b) (6)

Yours Sincerely,

Carla Vinals
Digitally signed
by Carla Vinals
Date:
2020.12.10
21:01:27 -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