

IND Number 27073
Sequence No. 0017

December 15, 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
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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

1.6.2 VRBPAC Sponsor Briefing Document – DS2 – (word version)

1.6.2 VRBPAC Sponsor Briefing Document – Addendum (word version)

1.11.3 Response to Comments – IR 18

1.11.3 Response to Comments – IR 19 – Item 1

1.11.3 Response to Comments – IR 20

5.3.5.1 mRNA-1273-P301:

mRNA-1273-P301_FDA Request #18_Narratives Facial Swelling

mRNA-1273-P301_Data Blinding Plan (DBP) Version 7.0 – 13December2020

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

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by Carla Vinals
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