

IND Number 27073
Sequence No. 0015

December 13, 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

1.11.3 Response to Comments – IR 17 – Items 1 – 2

1.11.3 Response to Comments – IR 17 – Item 3

1.11.3 Summary Table - Solicited Adverse Reactions_IR#17

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

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

5.3.5.1 mRNA-1273-P301:

mRNA-1273-P301_FDA Request #17 Item 3_Non-Serious Anaphylaxis Subject US3262133

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,

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