

IND Number 27073
Sequence No. 0016

December 14, 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
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Submission Type: VRBPAC Briefing Document – Addendum
Final VRBPAC Slide Deck

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 Final version of the Core Presentation for the Vaccines and Related Biological Products Advisory Committee scheduled for 17 December 2020

1.6.2 VRBPAC Sponsor Briefing Document – Addendum

The response to comments regarding CMC information (IR #10) received on December 08, 2020 was submitted to IND 019745 in Sequence 0087 on December 14, 2020.

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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