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Sequence No. 0004

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Marion Gruber, PhD
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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 information requests (0001, 0004, 0005, 0006, 0007)

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 Request for Information: EUA27073 #0001-01Dec

1.11.3 – Subject Demographics and Other Baseline Characteristics: EUA27073 #0001-05Dec

1.11.3 – Response to Comments Regarding Clinical Datasets: EUA 27073 #0004-03Dec

1.11.3 – Response to Comments Regarding Summaries for Clinical Laboratory-Safety #0005-04Dec

1.11.3 – Response to Information Request – Summary of Severe-COVID-19 by Subject: EUA 27073 #0006-05Dec

1.11.3 – Response Comments Regarding Adverse events: EUA 27073 #0007 Q1-2-05Dec

5.3.5.1 – Baseline Demographics and Characteristics by Age Group: EUA 27073 #0001-05Dec

5.3.5.1 – mRNA-1273-P301 Severe Covid19 MW Forms: EUA 27073 #0006-05Dec

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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