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Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Document Control Center
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**Submission Type: Sponsor Briefing Document for VRBPAC, PVP Plan, Data Snapshot 2
Efficacy Topline Tables and Figures for mRNA-1273-P301, Response to
Comments related to Pregnancy, and additional Clinical 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 – Vaccines and Related Biological Products Advisory Committee Sponsor Briefing Document
- 1.11.3 – Response to Comments Regarding Pregnancy and Active Surveillance Studies – 02 December 2020
- 1.11.3 – Response to Comments Regarding Clinical Topics – 02 December 2020
- 1.11.4 – Submission Plan Supporting Emergency Use Authorization (EUA)
- 1.16.1 – Pharmacovigilance Plan
- 5.3.5.1 – mRNA-1273-P301 – Data Snapshot 2 Efficacy Topline Tables and Figures

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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