

**IND Number 27073**  
**Sequence No. 0002**

December 04, 2020

Marion Gruber, PhD  
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Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration  
Document Control Center  
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Silver Spring, MD 20993-0002

**Submission Type: Response to Information Request - Labeling**

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, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2). Reference is also made to the email from Goutam Sen received on December 01, 2020 with subject "CBER comments on your Fact Sheet Labels, EUA 27073".

This purpose of this submission is to provide the draft provider and recipient/caregiver fact sheets (clean and tracked changes) and the draft prescribing information (PI) (clean and tracked).

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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