

**EUA Number 27073**  
**Sequence No. 0019**

December 16, 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  
WO71, G112  
Silver Spring, MD 20993-0002

**Submission Type: Information Amendment – Chemistry, Manufacturing and Control**

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

1.11.1 Quality Information Amendment

3.2.P.5.4 Certificate of Analysis (CoA) Attachments for mRNA-1273 Drug Product Lots for Distribution under EUA:

- CoA Lot 7006520001 (Catalent Lot 057G20)
- CoA Lot 7006520002 (Catalent Lot 062G20)
- CoA Lot 7006520004 (Catalent Lot 032H20)
- CoA Lot 7006520005 (Catalent Lot 011J20)
- CoA Lot 7006520006 (Catalent Lot 025J20)
- CoA Lot 7006520007 (Catalent Lot 025J20-2)
- CoA Lot 7006520008 (Catalent Lot 029K20)
- CoA Lot 7006520009 (Catalent Lot 029K20-2)
- CoA Lot 7006520010 (Catalent Lot 039K20)
- CoA Lot 7006520011 (Catalent Lot 039K20-2)
- CoA Lot 7006520012 (Catalent Lot 037K20)
- CoA Lot 7006520013 (Catalent Lot 025L20)
- CoA Lot 7006520015 (Catalent Lot 026L20)

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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