

**BLA Number 125752**  
**Sequence No. 0017**

October 25, 2021

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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Silver Spring, MD 20993-0002

**Submission Type: Response to Information Request #8 received on October 06, 2021**

Dear Dr. Gruber:

Reference is made to BLA 125752 for the initial Biologics License Application (BLA) for mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2) currently under review with the agency.

The purpose of this submission is to submit a response to information request #8 received on October 06, 2021 regarding CMC: Analytical method procedure and validation.

If FDA has any questions, please do not hesitate to contact me directly at (617) 417-4428 or at [michelle.olsen@modernatx.com](mailto:michelle.olsen@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,

Michelle Olsen

Digitally signed by Michelle Olsen  
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