

**BLA Number 125752**  
**Sequence No. 0043**

December 27, 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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**Submission Type: Response to FDA Comments on Information Request #40 Received on  
21 December 2021, Information Requests #41 and #42a and #42b Received on  
23 December 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 provide responses for the following information requests:

- IR #40 regarding CMC information for the PAR for CPD and correction of fill volume presentations for Baxter Pharmaceutical Solutions, LLC.,
- IR #41 regarding the Lot Release Protocol template
- IR #42a USPI
- IR #42b regarding the bacterial endotoxin analytical method procedure and validation.

If FDA has any questions, please do not hesitate to contact me directly at (b) (6) or at 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**  
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