

**BLA Number 125752**  
**Sequence No. 0037**

December 16, 2021

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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**Submission Type: Response to FDA Labeling Comments Regarding Spikevax (IR#34)**  
**Updated Pharmacovigilance Plan**

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 revised labeling as requested in the comments provided on December 14 in IR #34. In addition, as requested in IR#31 an updated PVP is also included (clean and redline).

If FDA has any questions, please do not hesitate to contact me directly at (617) 417-4428 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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