

**IND Number 19745**  
**Sequence No. 0089**

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 Investigational New Drug Application (IND# 19745) for mRNA-1273, a messenger RNA (mRNA)-based active immunization to induce protective immunity against acute respiratory disease associated with the SARS-COV-2 virus (Sequence No. 0001, April 27, 2020).

Information concerning mRNA-1273 Drug Product Lot 7006520014 (Catalent Lot 038K20A) is being provided. This lot is subject of a deviation as the result of a leak prior to the filling operation.

Per a teleconference on December 16, 2020 with FDA (b) (6), the CofA for Lot 7006520014, the deviation investigation from Catalent (REC 283121), and the technical summary are being provided. The CofA is being submitted in Section 3.2.P.5.4 as an attachment to that section. At the request of FDA, this Quality Information Amendment is being simultaneously submitted to IND 19745 and EUA 27073.

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**  
Digitally signed  
by Carla Vinals  
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2020.12.16  
17:49:17 -05'00'

Carlota Vinals  
VP, Regulatory Affairs Strategy  
ModernaTX, Inc.  
200 Technology Square  
Cambridge, MA 02139  
Tel.: (b) (6); Fax: (b) (6)  
Email: (b) (6) @modernatx.com