

IND Number 19745
Sequence No. 0091

December 18, 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 6008620003 (Catalent Lot 027L20) 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 6008620003 (Catalent Lot 027L20), the deviation investigation from Catalent (REC 284379), 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). FDA has any questions, please do not hesitate to contact me directly at (b) (6) or at (b) (6)@modernatx.com.

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Yours Sincerely,

Carla Vinals

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