

EUA Number 27073
Sequence No. 0020

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 pre-assigned submission tracking number (STN) EUA 27073 for Emergency Use Authorization of the new drug mRNA-1273.

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 (John Eltermann, Robin Levis, Robert Sausville and Jerry Weir), 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,

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