

**IND Number 19745**  
**Sequence No. 0067**

November 11, 2020

(b) (6)  
/CBER  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**Submission Type: Response to FDA Request for Information**  
**Information Amendment – Chemistry, Manufacturing and Control**

Dear (b) (6)

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). Reference is also made to the Request for Information for additional facility information for the contract manufacturing facilities for mRNA-1273 manufacturing, Lonza Biologics (Portsmouth, NH) and Catalent Biologics, LLC (Bloomington, IN), received via email from (b) (6), post CBER teleconference, held on October 26, 2020.

The purpose of this submission is to submit the response document (Catalent) and revised 3.2.A.1 Facilities and Equipment {Lonza} CTD section with requested information. Also included in this submission is (b) (4)

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,

**Carlota Vinals**  
Digitally signed  
by Carlota Vinals  
Date: 2020.11.11  
07:16:07 -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