

IND Number 19745
Sequence No. 0041

September 30, 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).

The purpose of this submission is to provide manufacturing, analytical and Process Performance Qualification (PPQ) validation documentation for the (b) (4) of CX-024414 mRNA at the ModernaTX, Inc. manufacturing facility in Norwood, MA and the (b) (4) of CX-024414 mRNA at the Lonza Biologics, Inc manufacturing facility in Portsmouth, NH.

The revised CTD sections, as described in the following table, are being submitted including the final Certificates of Analysis for four additional CX-024414 lots, Lot 4007520001, Lot 4007520002, Lot 4007520003 and Lot 4007520004.

CTD Section		Changes
1.4.2	Letter of Authorization	<ul style="list-style-type: none"> Type V Letter of Authorization for Lonza Biologics, Inc facility (b) (4)
3.2.S.2.1 {CX-024414}	Manufacturer(s)	<ul style="list-style-type: none"> Addition of manufacturing and release testing activities for the (b) (4) of CX-024414 mRNA at the Lonza Biologics, Inc manufacturing facility in Portsmouth, NH
3.2.S.2.2 {CX-024414}	Description of Manufacturing Process and Process Controls	<ul style="list-style-type: none"> Addition of Process Description by Unit Operation including process controls Additional detail added to Process Flow Diagram
3.2.S.2.4 {CX-024414}	Controls of Critical Steps and Intermediates	<ul style="list-style-type: none"> Addition of Critical Process Parameter, Microbial Control strategy, in process holds, and hold time characterization studies
3.2.S.2.5 {CX-024414}	Process Validation and/or Evaluation	<ul style="list-style-type: none"> Addition of the process validation and process performance qualification per unit operation for the CX-024414 manufacturing process
3.2.S.2.6 {CX-024414}	Manufacturing Process Development	<ul style="list-style-type: none"> Addition of process characterization studies Addition of analytical assessment Addition of summary of specification changes Addition of summary of analytical changes
3.2.S.4.4 {CX-024414}	Batch Analyses	<ul style="list-style-type: none"> Addition of CX-024414 lots, Lot 4007520001, Lot 4007520002, Lot 4007520003 and Lot 4007520004 release testing and CofAs
3.2.S.6 {CX-024414}	Container Closure Systems	<ul style="list-style-type: none"> Addition of materials of construction, specifications, suitability and extractable leachable information for the CX-024414 container closure
3.2.S.7.1 {CX-024414}	Stability Summary and Conclusions	<ul style="list-style-type: none"> Revision of extension of use period strategy Addition of Lot 4007220003, 4007220004, 4007220005, 4007520001, 4007520002, 4007520003 and 4007520004 to scope of stability program (b) (4)
3.2.S.7.3 {CX-024414}	Stability Data	
3.2.A.1 {Catalent}	Facilities and Equipment	<ul style="list-style-type: none"> Addition of Facilities and Equipment information pertaining to Lonza Biologics, Inc manufacturing facility in Portsmouth, NH

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
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