

IND Number 19745
Sequence No. 0013

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Director, Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Document Control Center
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Submission Type: CMC Briefing Document

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 request a teleconference for CBER feedback. One of these topics is related to a request from CBER on June 26, 2020 related to a clinical lot consistency study. The other three matters are CMC focused.

The Sponsor has commenced Process Performance Qualification (PPQ) activities for the mRNA-1273 vaccine with the aim to enable a commercial manufacturing process for mRNA-1273 vaccine while concurrently conducting the Phase 2 and Phase 3 human clinical trials. These activities are being performed to provide the necessary amendments to the existing regulatory filings to support the initial validated manufacturing process by September 2020 in anticipation of distribution of an mRNA-1273 vaccine once sufficient human clinical data become available. This discussion would include:

- 1) The use of a multiple-dose vial that does not contain any preservative.
- 2) The fill volume for a multiple-dose vial.
- 3) Analytical comparability to support lot-to-lot consistency in lieu of a clinical lot consistency study.
- 4) Classification of materials for the CX-024414 mRNA.

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
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