

IND Number 19745
Sequence No. 0084

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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: Response to FDA Request for Information – CMC
Information Amendment – Module 4, Module 2
mRNA-1273-P203 TORO

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). Reference is also made to the information request that was sent by FDA via email on November 20, 2020 (concerning comments and questions regarding IND 19745 SN0053). The purpose of this submission is to submit the response document with the requested information and amended Module 3 sections as provided in the following table.

CTD Section		Changes
3.2.S.4.2{SM-102 LNP}	Analytical Procedures	• (b) (4)
3.2.S.4.2{mRNA-1273 LNP}	Analytical Procedures	• Addition of the SOP number for Bioburden testing conducted at Lonza (Section 3.2.S.4.2.11)

Also included in this submission are the Module 4 reports as requested by CBER and M2 Non-Clinical Overview and Summaries (2.4 and 2.6.1 thru 2.6.7). Additionally, the mRNA-1273-P203 transfer of regulatory obligations (TORO) is included in this submission.

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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