

IND Number 19745
Sequence No. 0030

September 04, 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: Type C Meeting Request and 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) and electronic correspondence between Jennifer White, ModernaTX, Inc. Senior Vice President Global Quality and (b) (6) FDA on August 4, 2020.

This submission includes Type C meeting teleconference request/background document. The purpose of the Type C interaction is to review the list of general overview items in anticipation of a pre-emergency use FDA visit. The Sponsor would like to provide the Agency with details on the manufacturing history and the future plans, the facility and laboratory upgrades, the existing quality systems and preparation activities underway. The strategy for validation, testing and related controls will be presented in order for the Agency to assess the GMP and scientific feasibility of the Sponsor's Norwood, MA GMP manufacturing facility. The Sponsor would also like to discuss other quality system related topics, such as lot release requirements, as part of that meeting.

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) (b) (6) at PPD (b) (6) or email at (b) (6)

Yours Sincerely,

Carlota Vinals Digitally signed
by Carlota Vinals
Date: 2020.09.04
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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