U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #4

Date: September 23, 2021

To: **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
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From: **Josephine Resnick, Ph.D.**
DVRPA/OVRR/CBER
Email: Josephine.Resnick@fda.hhs.gov

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Assays (Antibody Quantification)

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. We have the following request for additional information:

> Regarding the document titled Summary of Biomarker Assays Used in mRNA-1273 Program, based on the information summarized in Table 1, for Phase 3 study 301, the quantification of neutralizing antibodies (nAb) and binding antibodies (bAb) were each performed in two laboratories using different assays (nAb: Live Virus MN at Battelle or Pseudovirus VNA at Duke; bAb: Anti-S-2P IgG ELISA at PPD or Anti-S IgG Multiplex MSD at VRC VIP). Please describe which clinical samples were tested in each laboratory, the rationale for the segregation of the samples among the laboratories and the impact on the overall analysis of results.

Please confirm your receipt of this request, and provide your responses as an amendment to STN 125742 at your earliest convenience but no later than September 30, 2021.

Please contact me if you have questions and include Sudhakar Agnihothram (Sudhakar.Agnihothram@fda.hhs.gov) and Joseph Kulinski (joseph.kulinski@fda.hhs.gov) on all communications.