U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/1

Information Request #40

Date: December 21, 2021

To: **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
Email: Michelle.Olsen@modernatx.com

From: **Josephine Resnick, Ph.D.**
DVRPA/OVRR/CBER
Email: Josephine.Resnick@fda.hhs.gov

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: CMC

Our review of your August 16, 2021 submission (STN 125752/1) is ongoing. We have the following request for additional information:

Information Request

We reviewed the CMC information submitted to BLA 125752 and have the following comments:

1. Regarding the revised proven acceptable ranges (PARs) proposed for total cumulative process duration (CPD) of (b) (4) and cumulative time out of refrigeration (TOR) of (b) (4), please revise all mRNA-1273 Drug Product (DP) eCTD sections of the BLA where appropriate.
2. In section 3.2.P.2.3.1.2.3 *Characterization of Cumulative Process Duration,* please include:
   a. Available information to support the revised PARs for CPD and TOR such as the information provided to support the same changes under EUA 27073; e.g., release testing results, CPDs and TORS for all Catalent DP lots manufactured with exceeded or non-exceeded process durations up to September 2021.
   b. Available information on process duration deviations at Baxter and release testing results, CPDs and TORS for all Baxter DP lots manufactured with exceeded or non-exceeded process durations up to September 2021.

4. In section 3.2.P.3.3 *Description of Manufacturing Process and Process Controls {Baxter}*, you indicated that two mRNA-1273 DP multiple dose presentations with fill volumes of 6.3 mL and 8.0 mL are manufactured; however, the information provided for the Baxter manufacturing process in all other sections of the BLA, including the process validation section, is for the 8.0 mL fill volume. Please clarify and, if necessary, revise the appropriate sections of the BLA.

Please confirm your receipt of this request and submit your response as an amendment to STN 125752 as soon as possible but no later than December 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.