U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #7

Date: October 5, 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: Analytical method procedure and validation

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing.

We have the following request for additional information regarding the bacterial endotoxin, bioburden and sterility methods for testing CX-024414, mRNA-1273 and (b) (4) (b) (4) and drug product:

1. CX-024414
   - Please provide complete verification reports for CX-024414 Endotoxin tests performed both at Moderna TX and Lonza Portsmouth facilities to include product lot numbers tested, sample testing dilutions used in the test for interfering factors and their positive product control percent recoveries and selected optimal product testing dilution.

   - Please provide complete qualification reports for CX-024414 Bioburden tests performed both at Moderna TX and Lonza Portsmouth facilities to include the test sample volume, (b) (4) , product lot numbers tested, as well as (b) (4) .

2. mRNA-1273
    - Please provide a complete verification report for mRNA-1273 Endotoxin tests performed at Associates of Cape Cod, Inc. (ACC) to include product lot numbers tested, sample testing dilutions used in the test for interfering factors and their positive product control percent recoveries and selected optimal product testing dilution.

    - Please provide a complete qualification report for mRNA-1273 Bioburden test performed at Lonza Portsmouth to include the test sample volume, (b) (4) , product lot numbers tested, as well as (b) (4) (b) (4)

3. (b) (4)
    - (b) (4)

    - (b) (4)

    - (b) (4)

- **<u>Drug Product</u>**
    1. Bacterial Endotoxin Test (BET)
        - Please provide the current Standard Operating Procedure (SOP) and a complete verification report for SPIKEVAX drug product Endotoxin testing performed at ACC to include product lot numbers tested, sample testing dilutions used in the test for interfering

factors and their positive product control percent recoveries and selected optimal product testing dilution.

2. Sterility
   - Please provide the current SOP and complete qualification reports for SPIKEVAX drug product Sterility tests performed both at the Catalent Indiana and Baxter Pharmaceutical Solutions facilities including test sample volume, (b) (4), (b) (4), as well as product lot numbers tested.

Please confirm your receipt of this request, and provide your responses as an amendment to STN 125752 at your earliest convenience but no later than October 12, 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.