U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/1

Information Request #41

Date: December 23, 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: Lot Release Protocol Template:

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

Please note, the page numbers referenced below are from Adobe page numbering of the LRP template submitted in 125752/0.36.

Page 1 of 1:

1. Please align the selection “For Surveillance” under “Reason for Submission” so that it matches the rest of the reasons. Also, please leave a space under the “For Licensing Action” that looks like this:

   STN/Supp #:

   This is where you will list the STN and the supplement number for future licensing action submissions.

2. Please format the signature area at the bottom of page 1 as follows:

Signature: _____ Date: _____
Printed Name: _____
Title: _____

Please Note: A digital signature of the person responsible for signing the protocol is recommended. A handwritten signature and printed name are acceptable, but if a digital signature is used, the "Printed Name" can be deleted.

3. Please add an area for the electronic protocol number. This will need to be entered when the protocol is submitted electronically.

   Protocol #: _____

Note: The Product Release Branch (PRB), Division of Manufacturing and Product Quality (DMPQ) of OCBQ receives Drug Product lots and LRPs. These are submitted via an electronic gateway that is different from that used for electronic submissions to the product office. If you have not already done so, please contact Ms. Cheryl Hulme, PRB, DMPQ at Cheryl.Hulme@fda.hhs.gov to obtain information needed to access the gateway.

Pages 1 through 9 of 9:

4. Please format the information at the top left of each page to look like this:

   cc: 125752_0/2256/FC
   Lot Number: _____
   Licensed Name of Product: COVID-19 Vaccine, mRNA

Note: Please include this information (the three lines) at the top left corner of every page in the protocol. The reason for submission should be documented on the first page only and no other pages.

Page 8 of 9:

As endotoxin results are reported as EU/mL, please keep units consistent with Table 1 (Page 4 of 9).

Page 9 of 9:

Please include the sterility test method (e.g., Membrane Filtration or Direct Inoculation).

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 January 5, 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.