U.S. FOOD & DRUG ADMINISTRATION

Response to Waiver Request/Advice

Our Reference: STN: 125752/2

Date: September 21, 2021

To: **Michelle Olsen, Ph.D.**
Moderna TX, 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 Waiver Request

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. We have the following response to your request that Spikevax be placed on surveillance in lieu of routing release testing:

- CBER does not agree with placing Spikevax on surveillance at the time of licensure and expects you to submit samples and protocols in accordance with 21 CFR 610.2 for official release. CBER will work with Moderna to establish a lot release protocol and to facilitate lot release through mechanisms such as concurrent testing.
- Please note the following:
  a) Lot Release Protocols (LRPs) and samples for lot release are submitted to the Product Release Branch (PRB), Division of Manufacturing and Product Quality (DMPQ), Office of Compliance and Biologics Quality (OCBQ). The LRPs are submitted via an electronic portal that is different from that used for electronic submissions to OVRR. Please contact Mr. Joseph Quander, Branch Chief, PRB, at Joseph.Quander@fda.hhs.gov to obtain information needed to access the gateway and to ship samples for testing.
  b) The LRP template you submitted in your application is under review; when CBER is satisfied that the information provided in the template is acceptable, we will notify you that it can be used. Please do not submit completed LRPs until notified. At this time, you will also be notified of the number of vials to submit to CBER for lot release.

c) CBER will request samples and reagents to implement and conduct lot release testing during the review of your BLA; the shipping information for those samples and reagents will be included in the information request.
d) If you plan to release lots at the time of approval (launch lots), CBER will work with you to facilitate release of those lots.

Please confirm your receipt of this request, and let me know if you have questions. Please include Sudhakar Agnihothram (Sudhakar.Agnihothram@fda.hhs.gov) and Joseph Kulinski (joseph.kulinski@fda.hhs.gov) on all communications.