U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #3

Date: September 22, 2021

To: **Michelle Olsen, Ph.D.**
Moderna TX, 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: 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 your assay for product-related impurities:

- According to your pre-BLA briefing document submitted on May 19, 2021, the Ion Pair Reversed Phase High Performance Liquid Chromatography (IP-RP-HPLC) method (SOP-0996) for analysis of mRNA purity in the CX-024414 mRNA Drug Substance (DS), mRNA-1273 LNP DS, and mRNA-1273 Drug Product (DP) was modified to improve (b) (4) . However, the updated method (SOP-1142) and its validation have not been submitted to the BLA. Please provide the updated SOP-1142 and full validation of the method or confirm your intent to use the original method as described in SOP-0996.

- If you intend to use the original method (SOP-0996) for Drug Substances (DS) and Drug Product (DP) release testing, please provide (b) (4) that were used in the validation study.

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 October 10, 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.