U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #47

Date: January 24, 2022

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

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

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Clinical

Our review of your August 24, 2021 submission (STN 125752/1) is ongoing. We have the following request for additional information regarding the lot release protocol template:

We note that participant # mRNA-1273-P301-US335-2594 was a 31-year-old Hispanic female with negative baseline serostatus who reported Grade 4 fatigue and arthralgia after Dose 1 and withdrew from study vaccination (did not receive Dose 2), but continued to be followed in the study until Part B.

Please provide a case narrative for this participant that provides all available information about these events, including whether this participant required a visit to the Emergency Room or require hospitalization (Why were these adverse reactions considered Grade 4?).

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 25, 2022.

Please contact me if you have questions and include Josephine Resnick (josephine.resnick@fda.hhs.gov) and Joseph Kulinski (joseph.kulinski@fda.hhs.gov) on all communications.