U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #48

Date: January 26, 2022

To: **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
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From: **Joseph Kulinski, Ph.D.**
DVRPA/OVRR/CBER
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Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Clinical data – Unsolicited Adverse Events

In Section 6.1 of your PI, under Unsolicited Adverse Events, in discussion of delayed injection site reactions, the current text reads:

Delayed injection site reactions that began >7 days after vaccination were reported in 2.4% of vaccine recipients and 1.4% of placebo recipients.

Please indicate how these percentages were obtained. We note that in Table 14.3.1.21.1.3.3 of your CSR, subjects reporting solicited injection site reactions after any dose with onset >7 days was 1.4% (n=219) in the mRNA-1273 group and 0.7% (n=100) in the placebo group. Please clarify this discrepancy, and if changes are needed, please submit a revised PI for our review.

Please confirm your receipt of this request and submit your response as an amendment to STN 125752 as soon as possible. Please include Sudhakar Agnihothram (sudhakar.agnihothram@fda.hhs.gov) and Josephine Resnick (josephine.resnick@fda.hhs.gov) on all communications.