U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #30

Date: December 10, 2021

To: **Michelle Olsen, Ph.D.**
ModernaTX, 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: Unsolicited AEs

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. We have the following request for additional information regarding unsolicited adverse events.

Unsolicited AEs

1. For the cases of facial paralysis/Bell's palsy in the mRNA-1273 group and the placebo arm of Part A, please provide the following information:
    a. Onset of facial paralysis/Bell's palsy relative to the most recent vaccination, including whether it followed dose 1 or dose 2.
    b. Other underlying risk factors that could be associated with Bell's palsy.
2. We note an imbalance in cases of herpes zoster in the mRNA-1273 arm versus the placebo arm. For each of the cases of herpes zoster in the mRNA-1273 and placebo groups, please provide the following information, for Part A overall and for those within 28 days after any vaccination:
    a. Onset relative to the most recent vaccination, including whether it followed dose 1 or dose 2.
    b. Please also include details of any underlying risk factors in these participants.
3. For the mRNA-1273 group and the placebo group, please provide the number of participants who experienced a hypersensitivity-related event as a TEAE within 7 days of any vaccination.

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 December 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.