U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #43

Date: January 7, 2022

To: **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
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From: **Sudhakar Agnihothram, Ph.D.**
DVRPA/OVRR/CBER
Email: Sudhakar.Agnihothram@fda.hhs.gov

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Clinical IR – Safety Data For P301

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing.

In Part A of Study P301, for adverse events of herpes zoster within 28 days after any vaccination, in the mRNA-1273 group and placebo group, please provide the following details in a Word table:

Investigational Product	Age/Sex	Onset after Dose 1 or 2	Day of Onset after most recent vaccination	Resolution status	Grade/SAE	Possible Risk Factors	Related[a]
mRNA-1273							
Placebo							

[a] Classification of events as SAEs and relatedness determined by study investigators

Please confirm your receipt of this request. Please submit your response by 1/10/2022.

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.