U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #17

Date: November 5, 2021

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: Pharmacovigilance Plan

Our review of your pharmacovigilance plan for SPIKEVAX under BLA STN 125752/2 is ongoing. We have the following comments regarding postmarketing studies. Please propose:

1. Postmarketing observational safety study(ies) to evaluate the occurrence of myocarditis and pericarditis following administration of SPIKEVAX, to quantify the magnitude of risk of myocarditis and pericarditis by age, sex, and dose.
2. Prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination, including assessment of recovery status, risk factors, and identification of serious cardiovascular outcomes, and analyses by age, sex, and dose.
3. Prospective study to assess the incidence of subclinical myocarditis following SPIKEVAX, including analyses by age, sex, and dose.

For the above studies, include the following information in your proposal: study designs, sample sizes and justification of sample sizes including number of subjects ≤30 years of age, information to be collected at baseline, frequency and methods for follow-up data collection, plan for duration of long term follow-up and information to be collected in follow-up, study timeline and milestone dates (final protocol submission date, study completion date, and final study report submission date; please provide dates in mm/dd/yyyy format).

Please provide a response to this information request by November 10, 2021 and contact me if you have questions and include Sudhakar Agnihothram (sudhakar.agnihothram@fda.hhs.gov) and Josephine Resnick (josephine.resnick@fda.hhs.gov) on all communications.