U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #22

Date: November 19, 2021

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

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

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Postmarketing Studies

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. We have the following requests for additional information:

FDA is reviewing your response regarding postmarketing studies for SPIKEVAX. You have stated that evaluation of the occurrence of myocarditis and pericarditis following administration of SPIKEVAX and quantification of the magnitude of risk by age, sex and dose will occur primarily in two large secondary database studies, mRNA-1273- P903 and mRNA-1273-P904. Please provide the following information on the sample size for these studies:

- mRNA-1273- P903: It is stated that as per the most recent interim report, this study included >1.3 million vaccinated individuals 18 – 29 years of age. Please provide an estimated minimum number of Spikevax recipients <30 years of age that this data source will be able to identify.

- mRNA-1273- P904: It is estimated that the participating databases together will be able to identify at least 431,216 recipients of Spikevax. Does 431,216 recipients refer to individuals <30 years? If not, then please provide an estimated minimum number of Spikevax recipients <30 years of age that this data source will be able to identify.

Please confirm your receipt of this request, and provide your responses as an amendment to STN 125752 at your earliest convenience but no later than November 22, 2021.

Please 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.