U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #16

Date: November 5, 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: EU Risk Management Plan

The EU Risk Management Plan submitted in your BLA 125752/2 is under ongoing review. Please submit the protocol or protocol synopsis for postmarketing vaccine effectiveness Study mRNA-1273-P901 to your BLA by November 9, 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.