U.S. FOOD & DRUG ADMINISTRATION

# Information Request

**Our Reference: STN: 125752/2**

**Information Request #32**

**Date:** December 10, 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:** Analytical method procedure and validation

In reviewing your response to information request (IR) #26, we have an additional IR regarding the endotoxin in the Drug Product using the (b) (4) LAL procedure.

1. We would like to clarify that we do not object to the DP release test for endotoxin being performed on a sample that has been extracted with (b) (4) However, in addition to those results, we request you measure and report the results from samples that are not treated prior to release testing so that the total endotoxin activity of the product is reported and the specification for the product as a whole, is met. Please state the date by which data will be submitted to support the additional method. Please request a telecon if you would like to discuss this request.

2. Please provide the positive product control (PPC) recovery for drug product (beginning, middle and end samples) tested under Associates of Cape Cod (ACC) report numbers# 0121-012TESVR, 0421-290TESCVR, 0421-290TESCVR, 0521-099TESCVR, 0820-082TESVR and 1220-223TESVR.

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 December 17, 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.