



Information Request

Our Reference: STN: 125752/2

Information Request #42

Date: December 23, 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

We have reviewed your December 20, 2021 response to information request (IR) #32, regarding the endotoxin testing of Drug Product (DP) using the (b) (4) Limulus Amebocyte Lysate (LAL) procedure. Please provide us with a timeframe (post regulatory action on the BLA) by which you plan on submitting the additional method development/expanded endotoxin testing on whole DP ((b) (4) procedure).

Please confirm your receipt of this request and submit your response as an amendment to STN 125752 as soon as possible but no later than December 29, 2021. If clarification is needed, please request a technical call as soon as possible and include Sudhakar Agnihothram (sudhakar.agnihothram@fda.hhs.gov) and Josephine Resnick (josephine.resnick@fda.hhs.gov) on all communications.