



Information Request

Our Reference: STN: 125752/1

Information Request #46

Date: January 14, 2022

To: **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
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From: **Josephine Resnick, Ph.D.**
DVRPA/OVRR/CBER
Email: Josephine.Resnick@fda.hhs.gov

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Lot release protocol template

Our review of your August 16, 2021 submission (STN 125752/1) is ongoing. We have the following request for additional information regarding the lot release protocol template:

Please note, the page numbers referenced below are from Adobe page numbering of the LRP template submitted in 125752/0.43.

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Please change "Protocol #:" to "Electronic Filename:" to facilitate future submissions to FDA's electronic gateway.

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Appendix 1, for endotoxin test details for the CX-024414 mRNA:

- Please correct the unit of standard endotoxin concentration to EU/mL (not (b) (4)).
- Please use EU/mL for endotoxin results in the product test summary table.
- (b) (4) for the average endotoxin result unit is acceptable because this aligns with the CX-024414 specification (b) (4) (b) (4)

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 January 17, 2022.

Please contact me if you have questions and include Sudhakar Agnihothram (sudhakar.agnihothram@fda.hhs.gov) and Joseph Kulinski (joseph.kulinski@fda.hhs.gov) on all communications.