



Information Request

Our Reference: STN: 125752/2

Information Request #10

Date: October 20, 2021

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: Manufacturing

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

1. In section 3.2.S.2.3.2.2, Plasmid Manufacturing, (b) (4) and Aldevron, Fargo, ND (Aldevron), were listed as manufacturers for the linearized plasmid DNA (pDNA), however, in section 3.2.S.2.1, Manufacturer(s) {CX-024414}, Aldevron was listed as the only manufacturer for the linearized pDNA template.
 - a. Please clarify if (b) (4) is involved with the manufacture of the linearized pDNA template for SPIKEVAX, including but not limited to release testing, stability testing and storage unit operations.
2. Please describe the primary container closure system used in storing and shipping the linear DNA template to (b) (4) for further processing.
3. Please provide the maximum hold time for each manufacturing step of the linear DNA template and provide the at scale (b) (4)

4. Please provide the shipping validation summary for shipments of linear DNA template from Aldevron to (b) (4) . Also, please clarify if all shipments of linear DNA template will be temperature-monitored.

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 3, 2021.

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.