



Information Request

Our Reference: STN: 125752/2

Information Request #25

Date: November 29, 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: CMC Information

We are reviewing the CMC information submitted in the BLA STN 125752 regarding the (b) (4), mRNA-1273 LNP DS and mRNA-1273 Drug Product (DP) and have the following questions:

The following comments pertain to the (b) (4):

1. (b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
2. (b) (4)
(b) (4)
 - a. (b) (4)
 - b. (b) (4)
(b) (4)
 - c. (b) (4)

(b) (4)
(b) (4) .

3. (b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)

The following comment pertains to stability studies:

4. Please provide the most current stability data for (b) (4)
(b) (4) mRNA-1273 DS and DP and for any scale B or clinical
and developmental lots.

The following clarification pertains to re-processing:

5. The description of the manufacturing processes for the (b) (4)
(b) (4), mRNA-1273 LNP DS, and mRNA-1273 DP
indicate that reprocessing is not performed for any process steps. However,
process validation protocols were included for a (b) (4) step for (b) (4)
(b) (4) Please clarify
if implementation of re-processing to include (b) (4) step will be
requested for these process steps.

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
15, 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.