

January 4, 2022

Please Note,

A review of PRB records indicates that there are no pending lots or issues that would affect the approval of the stated STN.

125752/0

Biologist, Product Release Branch

CBER/OCBQ/DMPQ

WO, Building 71, Room 6062

240-402-9165 (main)/ 240-402-5839 (office)

Leyla.beshir@fda.hhs.gov

[Lot Release Information](#)



From: Resnick, Josephine <Josephine.Resnick@fda.hhs.gov>

Sent: Tuesday, January 4, 2022 11:03 AM

To: CBER Lot Clearance <cberlotclearance@fda.gov>

Cc: Kulinski, Joseph <Joseph.Kulinski@fda.hhs.gov>; Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>

Subject: Lot Clearance request: STN 125752 (SPIKEVAX)

OVRP/DVRPA would like to submit the following Lot Clearance request:

Please confirm that there are no lots associated with this original BLA Submission:

STN: 125752

Product: COVID19 Vaccine, mRNA , SPIKEVAX

Subm Type\Subtype: Original BLA

Short Summary: Original BLA seeking approval for COVID19 Vaccine, mRNA Vaccine (SPIKEVAX)

Manufacturer's license number: Not yet issued

Company/Address:

ModernaTX, Inc.
200 Technology Square
Cambridge, MA 02139

Action Due Date: (Accelerated review) – January 31, 2022

Thanks!

Jo Resnick

Josephine Resnick, Ph.D

Biologist (Primary Reviewer)

Center for Biologics Evaluation and Research

Office of Vaccines Research and Review

U.S. Food and Drug Administration

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