DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

MEMORANDUM

Date: January 20, 2022

From: Marie J. Anderson, MS, PhD
Division of Biological Standards and Quality Control (DBSQC)
Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

To: Biologics License Application Submission Tracking Number 125752

Subject: Review of Lot Release Protocol (LRP) Template for COVID-19 mRNA Vaccine

Through: Varsha Garnepudi, Branch Chief QAB/DBSQC/CBER/FDA
Maryna Eichelberger, PhD, Director DBSQC/OCBQ/CBER/FDA
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Cc: Sudhakar Agnihothram, PhD, Chair, BLA Review Committee, DVP/OVRR/CBER/FDA
Joseph Kulinski, PhD, RPM, DVRPA/OVRR/CBER/FDA
Josephine Resnick, PhD, RPM, DVRPA/OVRR/CBER/FDA

Applicant: ModernaTX, Inc.
Product: COVID-19 Vaccine, mRNA

Trade Name: SPIKEVAX

Executive Summary: The LRP template for COVID-19 Vaccine, mRNA submitted in amendment 125752/0.47 on January 18, 2022 is acceptable for use.

1 General Information

1.1 CMC Review Identifiers and Dates

1.1.1 **Biologics License Application (BLA) Submission Tracking Number (STN):** 125752

1.1.2 **Submission received by CBER:** August 24, 2021

1.1.3 **Review completed:** January 18, 2022

Material Reviewed: BLA 125752

1.1.4 **Related Master File, INDs and BLAs:** N/A

2 Review

2.1 Documents Reviewed

LRP template submitted on August 16, 2021 in amendment 125752/0.1

Response and LRP template submitted on December 15, 2021 in amendment 125752/0.36

Response and LRP template submitted on January 18, 2022 in amendment 125752/0.47

2.2 Review

ModernaTX, Inc. submitted an LRP template in amendment 125752/0.1 on August 16, 2021. This LRP template was reviewed by OVRR/DVP, OCBQ/DBSQC, and OCBQ/DMPQ/PRB with comments.

An information request (IR) for a revised LRP template was sent on December 7, 2021. A response and revised LRP template were submitted to amendment 125752/0.36 on December 15, 2021. This response and LRP template were reviewed by OVRR/DVP, OCBQ/DBSQC, and OCBQ/DMPQ/PRB with comments provided.

An IR for a revised LRP template was sent on January 14, 2022. A response and revised LRP template were submitted in amendment 125752/0.47 on January 18, 2022. This response and LRP template were reviewed by OCBQ/DBSQC, and OCBQ/DMPQ/PRB with no comments provided.

3 Conclusions

The LRP template for COVID-19 Vaccine, mRNA submitted in amendment 125752/0.47 on January 18, 2022 is acceptable for use. This template may be used for future lot release submissions.