Our STN: BL 125752/68

SUPPLEMENT APPROVAL
PMR FULFILLED

ModernaTX, Inc.
Attention: Michelle Olsen
200 Technology Square
Cambridge, MA 02139

September 11, 2023

Dear Dr. Olsen:

We have approved your request received March 28, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (SPIKEVAX) manufactured at Catalent Indiana, LLC (Bloomington, IN) and Patheon Manufacturing Services, LLC (Greenville, NC) to include: use in individuals 12 through 17 years of age, use as a single dose for individuals 12 years of age and older, the 2023-2024 Formula, manufacturing and quality control testing of 5-dose vials (0.1 mg/mL mRNA), and all associated labeling revisions.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT04649151, NCT04470427, NCT04927065, and NCT04405076.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling Package Insert submitted under amendment 44, dated September 8, 2023, Patient Package Insert submitted under amendment 42, dated September 8, 2023, and the draft carton and container labels for single dose vials, multiple-dose vials and single dose pre-filled syringes submitted under amendment 6, dated June 22, 2023.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert and Patient Package Insert submitted on September 8, 2023. Information on submitting SPL files

using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on June 22, 2023, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125752 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the (b) (6) at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement #1 identified in the approval letter for BLA STN BL 125752/0 for COVID-19 Vaccine, mRNA (SPIKEVAX). The requirement addressed in this submission is as follows:

1. Deferred pediatric study under PREA (Study mRNA-1273-P203) to evaluate the safety and effectiveness of SPIKEVAX in children 12 years through 17 years of age.

   Final Protocol Submission: January 31, 2022

   Study Completion Date: April 30, 2024

   Final Report Submission: July 31, 2024

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages younger than 2 years of age because there is evidence strongly suggesting that a single dose of SPIKEVAX would be ineffective in this pediatric group. Seroprevalence data suggest that a significant proportion of the population younger than 6 months of age are naïve to SARS-CoV-2. Data from clinical studies in individuals 6 months through 23 months of age strongly suggest that a single dose of SPIKEVAX would be ineffective in individuals younger than 2 years of age.

We are deferring submission of your pediatric study for individuals 2 years through 11 years of age for this application because this product is ready for approval for use in individuals 12 years of age and older and the pediatric study has not been completed.

Your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is a required postmarketing study. The status of this postmarketing study must be reported according to 21 CFR 601.28 and section 505B(a)(3)(B) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an **Annual Status Report of Postmarketing Study Requirement/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of BLA STN BL 125752 until all

requirements and commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. This required study is listed below:

1. Deferred pediatric study under PREA (Study mRNA-1273-P204) to evaluate the safety of a single dose of SPIKEVAX in children 2 years through 11 years of age.

   Final Protocol Submission: February 28, 2022 (submitted)

   Study Completion Date: December 31, 2023

   Final Report Submission: March 31, 2024

Submit the protocol to your IND 19745, with a cross-reference letter to BLA STN BL 125752 explaining that this protocol was submitted to the IND.

Submit the final study report to this BLA STN BL 125752. In order for your PREA PMR to be considered fulfilled, you must submit and receive approval of either an efficacy or a labeling supplement. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated as:

- **Required Pediatric Assessment(s)**

This product is appropriately labeled for use in children 12 years through 17 years of age for this indication. Therefore, no additional studies are needed in this pediatric group.

We note that you have fulfilled the pediatric study requirement for children 12 years through 17 years of age for this application.

We will include the information contained in the above-referenced supplement in your BLA file.

Sincerely,

(b) (6)

Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research