Our STN: BL 125835/6

SUPPLEMENT APPROVAL
August 27, 2025

ModernaTX, Inc.
Attention: (b) (6)
325 Binney Street
Cambridge, MA 02142

Dear (b) (6):

We have approved your request received June 06, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (MNEXSPIKE), manufactured at (b) (4) to include the 2025-2026 Formula and associated labeling revisions for use in individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT05815498.

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 16, dated August 01, 2025, Patient Package Insert submitted under amendment 5, dated July 10, 2025, and the draft carton and container labels submitted on June 06, 2025.

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 submitted on August 1, 2025, and Patient Package Insert, submitted on July 10, 2025. 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 06, 2025, 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 125835 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitment as described in your correspondence submitted under amendment 22 on August 22, 2025, as outlined below:

1. A Phase 3b/4, Open-label, Single Arm Study to Evaluate the Immunogenicity and Safety of mRNA-1283.251 in Individuals ≥65 Years and ≥12 to <65 Years with Risk Factors for Severe COVID-19 (mRNA-1283-P401 Subprotocol 01).

    Final Protocol Submission: June 20, 2025 (Submitted)

    Study Initiation: July 21, 2025 (Completed)

    Protocol Amendment Submission: September 30, 2025

    Part A Data Memo: December 31, 2025

    Part B Interim Results: April 30, 2026

    Study Completion: May 31, 2026

    Final Report Submission: October 31, 2026

We acknowledge your written commitment as described in your correspondence submitted under amendment 23 on August 26, 2025, as outlined below:

2. A Phase 4 Randomized, Observer Blind, Placebo-controlled Study to Evaluate the Safety of mRNA-1273 and mRNA-1283 Variant-containing Formulations in Adults 50 to 64 Years of Age without High-Risk Conditions for Severe COVID-19.

    Study Initiation: November 30, 2025

    Study Completion: January 31, 2027

    Final Report Submission: January 31, 2028

Please submit clinical protocols and interim reports to your IND 27196, and cross-reference letters to BLA STN BL 125835 explaining that these protocols and interim reports were submitted to the IND.

If the information in the final study reports support a change in the labeling, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Status Update**

- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of BLA STN BL 125835 until all requirements and commitments subject to the reporting requirements of section 506B of the Federal Food, Drug, and Cosmetic Act (FDCA) are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

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

Sincerely,

David C. Kaslow, M.D.
Director, Office of Vaccines Research and Review
For (b) (6)
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research