Our STN: BL 125752/381

SUPPLEMENT APPROVAL
RELEASE FROM 506B POSTMARKETING COMMITMENT
NEW 506B POSTMARKETING COMMITMENT

August 27, 2026

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

Dear (b) (6):

We have approved your request received June 5, 2026, 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 the ModernaTX, Inc. (b) (4)); Catalent Anagni S.r.l (Anagni, Italy); Rovi Pharma Industrial Services; S.A. San Sebastián de los Reyes (Madrid, Spain); Rovi Pharma Industrial Services, S.A., Julián Camarillo (Madrid, Spain); Rovi Pharma Industrial Services, S.A. Alcala de Henares (Madrid, Spain); and (b) (4)); to include the 2026-2027 Formula and associated labeling revisions.

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 4, dated July 22, 2026, Patient Package Insert submitted under amendment 3, dated July 16, 2026, and the draft carton labels submitted under Amendment 12, dated August 25, 2026, and container labels submitted on June 5, 2026.

We acknowledge your commitment to implement the carton labeling changes approved under this supplement for SPIKEVAX 2026-2027 Formula, at the next printing. We recognize that immediate reprinting of labels to incorporate the FDA-requested revisions would significantly impact the timely availability of SPIKEVAX 2026-2027 Formula supply for the 2026–2027 season.

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 July 22, 2026, Patient Package Insert, submitted July 16, 2026. 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 labels submitted on August 25, 2026 and container labels submitted on June 5, 2026, 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 Advertising and Promotional Labeling Branch 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 commitments as described in your correspondence of August 14, 2026, as outlined below:

1. A Phase 3b/4 Randomized, Open-label Study to Evaluate Immunogenicity and Safety of MNEXSPIKE and SPIKEVAX 2026-2027 Formula in Individuals ≥65 Years of Age and 12 to <65 Years of Age With Risk Factors for Severe COVID-19

Final Protocol Submission:	September 18, 2026
Study Initiation:	November 16, 2026
Study Completion:	January 15, 2027
Interim Results:	March 26, 2027
Final Report Submission:	June 15, 2027

2. A Phase 3b/4, Open-label, Single Arm Study to Evaluate the Safety and Immunogenicity of SPIKEVAX 2026-2027 Formula in Individuals ≥6 months to <12 Years of Age with Risk Factors for Severe COVID-19

Final Protocol Submission:	September 18, 2026
Study Initiation:	December 31, 2026
Study Completion:	June 30, 2027
Interim Results:	September 17, 2027
Final Report Submission:	December 17, 2027

Please submit the clinical protocols and the interim results to your IND 19745, and cross-reference letters to BLA STN BL 125752 explaining that these protocols and interim results were submitted to the IND.

If the information in the final study report supports 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 125752 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.

RELEASE FROM POSTMARKETING COMMITMENT

We also refer to your submission received August 26, 2026, requesting release from the following postmarketing commitment (PMC) identified in the August 27, 2025, approval letter.

STN: BL 125752/305

PMC 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

We have completed the review of your submission and conclude that you are released from the above PMC because of operational and feasibility challenges that impacted the conduct of these studies as originally designed.

The above PMC will be replaced by the new PMCs described below.

NEW POSTMARKETING COMMITMENTS SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

3. A nonclinical study to assess biodistribution and persistence of COVID-19 vaccine-derived Spike protein following SPIKEVAX administration

   Analytical Method Characterization

Final Protocol Submission:	October 15, 2026
Study Initiation:	November 2, 2026
Study Completion:	January 18, 2027
Final Report Submission:	February 15, 2027

   Organ/Tissue-Level Characterization of Spike Persistence

Final Protocol Submission:	October 15, 2026
Study Initiation:	January 4, 2027
Study Completion:	January 18, 2027
Final Report Submission:	June 15, 2027

4. A Phase 4 Retrospective Integrated Analysis of SPIKEVAX Clinical Trial Data: Evaluation of Symptom Clusters Potentially Consistent with Post-COVID Vaccination Syndrome as Described in Published Literature

Final Protocol Submission:	September 18, 2026
Study Initiation:	October 31, 2026
Final Report Submission:	December 15, 2026

Please submit protocols to your IND 19745, and a cross-reference letter to this BLA 125752 explaining that these protocols were submitted to the IND.

If the information in the final study report supports 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**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

When you have fulfilled your commitment, submit your final report as **Postmarketing Commitment – Final Study Report** or **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 days of the anniversary date of the approval of the BLA until all Requirements and Commitments subject to the reporting requirements of section 506B of the 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, MD
Director, Office of Vaccines Research and Review
For (b) (6)
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research