Our STN: BL 125752/276

SUPPLEMENT APPROVAL
PMRs FULFILLED
July 9, 2025

Moderna TX, Inc.
Attention: Brady Nesbitt
325 Binney Street
Cambridge, MA 02142

Dear Mr. Nesbitt:

We have approved your request received January 7, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for mRNA-1273 COVID-19 Vaccine (SPIKEVAX), manufactured at Rovi Pharma Industrial Services, S.A. Julian Camarillo (Madrid, Spain) to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals who are 65 years of age and older, or 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19, and to include a new 0.25 mL pre-filled syringe presentation.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT04796896, NCT04649151, and NCT05436834.

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 32 on July 9, 2025, Patient Package Insert submitted under amendment 29, dated July 8, 2025, and the draft carton and container labels submitted under amendment 20, dated June 20, 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 July 9, 2025, and Patient Package Insert submitted on July 8, 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 20, 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 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)).

FULFILLED POSTMARKETING REQUIREMENTS

This submission fulfills your postmarketing requirement #1 identified in the September 11, 2023, approval letter for BLA STN BL 125752/68 for COVID-19 Vaccine, mRNA (SPIKEVAX). The requirement addressed in this submission is as follows:

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.

This submission fulfills your postmarketing requirement #2 identified in the January 31, 2022, approval letter for BLA STN BL 125752/0 for COVID-19 Vaccine, mRNA (SPIKEVAX). The requirement addressed in this submission is as follows:

2. Deferred pediatric study under PREA (Study mRNA-1273-P204) to evaluate the safety and effectiveness of SPIKEVAX in children 6 months through <12 years of age.

We remind you that there are PMRs PMCs still open. 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 this BLA until all Requirements and Commitments subject to the reporting requirements of section 506B of the Federal Food, Drug, and Cosmetic Act are fulfilled or released. The status report for each study should include:

- the sequential number for each study;
- 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 https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments.

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 note that you have fulfilled the pediatric study requirement for ages 6 months through 11 years of age for this application.

POSTMARKETING COMMITMENT SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

1. A Phase 4, Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of mRNA-1273 Variant-containing Formulation in Adults 50 to 64 Years of Age Without Risk Factors for Severe COVID-19.

   We acknowledge the timetable you submitted on July 9, 2025, which states that you will conduct this study according to the following schedule:

   Study Start Date: November 30, 2025

   Interim Analysis Date: May 31, 2026

   Study Completion Date: July 31, 2026

   Final Report Submission Date: January 31, 2027

   Benefit-Risk Assessment Submission: May 31, 2027

Please submit the Interim Results to your IND 19745, and a cross-reference letter to BLA STN BL 125752 explaining that the submission was submitted to the IND. Please submit the Benefit-Risk Assessment to the BLA as a PMR/PMC Submission – Correspondence Status Update.

If the information in the final study report supports a change in the labeling, the final study report must be submitted as a supplement to the BLA. 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.

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

Sincerely,

Vinayak Prasad, MD, MPH
Director
Center for Biologics Evaluation and Research