Our STN: BL 125869/0

BLA APPROVAL
ACCELERATED BLA APPROVAL
AUGUST 5, 2026

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

Dear (b) (6):

Please refer to your Biologics License Application (BLA) received December 5, 2025, under section 351(a) of the Public Health Service Act (PHS Act) for Influenza Vaccine, mRNA (MFLUSIVA).

LICENSING

We have approved your BLA for Influenza Vaccine, mRNA effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Influenza Vaccine, mRNA under your existing Department of Health and Human Services U.S. License No. 2256. Influenza Vaccine, mRNA is indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine in persons 50 years of age and older. The indication for persons 65 years of age and older is approved under accelerated approval pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) and the regulations for accelerated approval, 21 CFR 601.41.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT06602024, NCT05415462, NCT05566639, NCT05827978, and NCT04956575.

ACCELERATED APPROVAL REQUIREMENTS

Under accelerated approval statutory provisions and regulations, we may grant marketing approval for a biological product on the basis of adequate and well-controlled studies establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. This approval requires you to study the biological product further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome.

Approval under these statutory provisions and regulations requires, among other things, that you conduct adequate and well-controlled studies to verify and describe clinical benefit attributable to this product. Clinical benefit is evidenced by effects such as demonstration of effectiveness against influenza disease in adults 65 years of age and older.

Accelerated Approval Required Study

We remind you of your postmarketing requirement (PMR) specified in amendment 121 submitted August 5, 2026.

1. To conduct a Pragmatic, Randomized Study to Evaluate Relative Vaccine Effectiveness of mRNA-1010 Versus High-Dose Influenza Vaccine in U.S. Adults ≥65 Years of Age (Study mRNA-1010-P910).

    Final Protocol Submission: May 22, 2026 (Submitted)

    Study Initiation: August 31, 2026

    Interim Study Report 1 Submission: December 31, 2027

    Interim Study Report 2 Submission: December 31, 2028

    Interim Study Report 3 Submission: December 31, 2029

    Study Completion: July 31, 2029

    Final Report Submission: May 31, 2030

We expect you to complete design, initiation, accrual, completion, and reporting of this study within the framework described in your letter of August 5, 2026.

Please submit the protocol and Interim Study Reports to your IND 27460, with cross-reference letters to this BLA, STN BL 125869 explaining that this protocol and the Interim Study Reports were submitted to the IND. Please refer to the sequential number for this study and the submission number as shown in this letter (STN BL 125869/0).

You must conduct this study with due diligence. If this required postmarketing study fails to verify that clinical benefit is conferred by Influenza Vaccine, mRNA, or is not conducted with due diligence, including with respect to the conditions set forth below, we may withdraw this approval.

You must submit reports of the progress of the study listed above, as required under section 506(c) of the FDCA, to this BLA 180 days after the date of approval of this BLA and approximately every 180 days thereafter (see section 506B(a)(2) of the FDCA) (hereinafter “180-day reports”).

You are required to submit two 180-day reports per year for each open study or clinical trial required under 506(c) of the FDCA. The initial report will be a standalone submission, and the subsequent report will be combined with your application's annual status report required under section 506B(a)(1) of the FDCA and 21 CFR 601.70. The standalone 180-day report will be due 180 days after the date of approval (with a 60-day grace period). Submit the subsequent 180-day report with your application's annual status report. Submit both of these 180-day reports each year until the final report for the corresponding study is submitted to the BLA.

Your 180-day report must include the information listed in 21 CFR 601.70(b). FDA recommends that you use form FDA 3989 PMR/PMC Annual Status Report for Drugs and Biologics, to submit your 180-day reports. Form FDA 3989, along with instructions for completing this form, is available on the FDA Forms web page at https://www.fda.gov/about-fda/reports-manuals-forms/forms.

Your 180-day reports, including both the standalone 180-day report submitted 180 days after the date of approval, and the 180-day report submitted with your annual status report, must be clearly designated as **180-Day AA PMR Progress Report.**

FDA will consider the submission of your annual status report under section 506B(a)(1) of the FDCA and 21 CFR 601.70, in addition to the submission of reports 180 days after the date of approval each year (subject to a 60-day grace period), to satisfy the periodic reporting requirement under section 506B(a)(2) of the FDCA. You are also required to submit information related to your confirmatory trial as part of your annual reporting requirement under section 506B(a)(1) of the FDCA until the FDA notifies you, in writing, that the Agency concurs that the study requirement has been fulfilled or that the study either is no longer feasible or would no longer provide useful information.

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 this letter until all Postmarketing Requirements and 506B Commitments are fulfilled or released.

Please submit the final study report as a supplement to this BLA, STN BL 125869. For administrative purposes, all submissions related to this postmarketing study requirement must be clearly designated as "**Subpart E Postmarketing Study Requirements**."

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture Influenza Vaccine, mRNA drug substance at your ModernaTX, Inc. (Moderna (b) (4)) facility located at (b) (4) and the (b) (4) . The final formulated product will be manufactured and filled at (b) (4)

(b) (4)
; and labeled and packaged at (b) (4)

You may label your product with the proprietary name MFLUSIVA and market it in cartons containing ten single-dose (0.38 mL) pre-filled syringes.

DATING PERIOD

The dating period for Influenza Vaccine, mRNA shall be 12 months from the date of manufacture, when stored in the commercial container closure system at the recommended long-term storage condition of 2ºC to 8ºC that may include up to 12 hours of storage at 8°C to 25°C. The date of manufacture shall be defined as the start date of labeling and packaging operations. Following the final (b) (4), no reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your RNA drug substance shall be (b) (4) when stored in the approved container closure system at (b) (4)

COMPARABILITY PROTOCOLS

This approval includes comparability protocols submitted in the initial submission for the following:

- VV-QUAL-036185, v1.0 for Implementation of ModernaTX (b) (4) as an Alternate Manufacturer for mRNA-1010 (b) (4)

- VV-QUAL-036184, v1.0 for Introduction of Annual Seasonal Influenza Strain(s) Update for mRNA-1010.

You should report information confirming that the changes meet the requirements specified in your approved comparability protocols as a Prior Approval Supplement (21 CFR 601.12(b)). You should include the information described in 21 CFR 601.12 (b)(3) in these supplements. Subsequent to the approval of your Prior Approval Supplements, you may distribute the product made using these changes.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on FORM FDA 3486 to the (b) (6) , electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations.

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

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of Influenza Vaccine, mRNA, or in the manufacturing facilities.

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 including Package Insert submitted under amendment 116, dated August 3, 2026, Patient Package Insert submitted under amendment 110, dated July 30, 2026, the draft package label submitted under amendment 50, dated May 12, 2026, and the draft container label submitted under amendment 38, dated April 24, 2026.

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 3, 2026, and Patient Package Insert submitted on July 30, 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.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels identical to the package label submitted on May 12, 2026, and container label submitted on April 24, 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 125869 at the time of use and include implementation information on Form FDA 356h.

PROMOTIONAL MATERIALS

Please note that the accelerated approval regulation concerning promotional materials (21 CFR 601.45) stipulates that all advertising and promotional labeling items that you wish to distribute in the first 120 days following approval, must have been received by FDA prior to the approval date. After approval, promotional items intended for dissemination after the first 120 days following approval must be submitted to the FDA at least 30 days prior to the anticipated distribution date. Please submit draft materials with a cover letter noting that the items are for accelerated approval, and an accompanying 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 advertisement and promotional labeling at the time of initial dissemination or publication, accompanied by FORM FDA 2253 (21 CFR 601.12(f)(4)).

Alternatively, you may submit promotional materials for accelerated approval products electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs* at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf.

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)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

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 infants 0 to <6 months of age because necessary studies are impossible or highly impracticable. This is because: (1) Immunogenicity studies alone would be insufficient to demonstrate the vaccine effectiveness in this age group because of the presence of maternal antibodies – a clinical endpoint efficacy study will be needed; and (2) completion of a multiple dose regimen (anticipated to be 2-dose regimen in this age group) in the narrow window prior to the influenza season would be logistically challenging and would likely require the study to take place over multiple influenza seasons.

We are deferring submission of your pediatric studies for infants, children, and adolescents 6 months to <18 years of age for this application because the pediatric studies should be delayed until additional safety or effectiveness data have been collected. The BLA contains clinical data to support the safety and effectiveness of MFLUSIVA in adults 50 years of age and older. The Applicant plans to establish the safety and effectiveness of MFLUSIVA in adults 18 years of age and older prior to enrolling infants, children, and adolescents 6 months to <18 years of age.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) 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.

Please label your annual report as an "**Annual Status Report of Postmarketing Requirement/Commitments**" and submit it to FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

2. Study #1: Deferred pediatric study under PREA to evaluate the safety, reactogenicity, and immunogenicity of MFLUSIVA in infants, children, and adolescents 6 months to <18 years of age.

   Final Protocol Submission: May 31, 2027

   Study Completion Date: July 31, 2029

   Final Report Submission: December 31, 2029

3. Study #2: Deferred pediatric study under PREA to evaluate the safety and effectiveness of MFLUSIVA in healthy children and adolescents 9 years to <18 years of age.

   Final Protocol Submission: May 31, 2028

   Study Completion Date: July 31, 2029

   Final Report Submission: December 31, 2029

4. Study #3: Deferred pediatric study under PREA to evaluate the safety and effectiveness of MFLUSIVA in children 3 years to <9 years of age.

   Final Protocol Submission: May 31, 2029

Study Completion Date: July 31, 2030

Final Report Submission: December 31, 2030

5. Study #4: Deferred pediatric study under PREA to evaluate safety, efficacy, and immunogenicity of MFLUSIVA in healthy infants and children 6 months to <36 months of age.

   Final Protocol Submission: May 31, 2029

   Study Completion Date: July 31, 2031

   Final Report Submission: December 31, 2031

Submit the protocols to your IND 27460, with cross-reference letters to this BLA, STN BL 125869 explaining that the protocols were submitted to the IND.

Submit final study reports to this BLA STN BL 125869. In order for your PREA PMRs 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 these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitment as described in your submissions dated August 4, 2026 (amendment 117), and August 5, 2026 (amendment 121), as outlined below:

6. Post-Authorization Active Surveillance Safety Study to Monitor Real-World Safety of MFLUSIVA (mRNA-1010) Vaccine for the Prevention of Influenza Disease in the United States (Study mRNA-1010-P901). This study will be a safety study to evaluate deaths in a randomized population and an observational study for safety outcomes including myocarditis, pericarditis, myopericarditis, and Guillain-Barré syndrome after receipt of MFLUSIVA.

   Final Protocol Submission: December 31, 2026

   Study Completion Date: December 31, 2030

   Final Report Submission: December 31, 2031

7. You commit to conduct and submit results of Study mRNA-1010-P304, an Exploratory Microneutralization Antibody Correlate of Risk Analysis for Influenza B/Victoria Lineage.

   Final Report Submission: December 31, 2026

8. A Phase 4, Randomized Study to Assess the Immunogenicity of an Updated mRNA Seasonal Influenza Vaccine Composition to evaluate the humoral immunogenicity of mRNA-1010 relative to that of a licensed high-dose comparator in adults ≥65 years of age assessed with assays using both egg- and cell-based viruses.

   Final Protocol Submission: September 14, 2026

   Study Initiation: October 15, 2026

   End of Season 1 Report: April 15, 2027

   Study Completion: November 30, 2027

   Final Report Submission: December 31, 2028

Please submit the clinical protocol and the End of Season 1 report to your IND 27460 and a cross-reference letter to this BLA, STN BL 125869 explaining that the protocol and the End of Season 1 report 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 this letter 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 https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

David C. Kaslow, MD
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research