Our STN: BL 125835/12

ASSIGN / APPROVE
July 3, 2025

ModernaTX, Inc.
Attention: (b) (6)
7550 Wisconsin Ave
Bethesda, MD 20814

Dear (b) (6) :

Submission Tracking Number (STN) BL 125835/12 has been assigned to your recent supplement to your Biologics License Application (BLA) for COVID-19 Vaccine, mRNA (MNEXSPIKE) received June 23, 2025. Your submission is in the form of a "Special Labeling Supplement – Changes Being Effected' as described under 21 CFR 601.12(f)(2)(ii).

We approved your request to supplement your Biologics License Application for MNEXSPIKE to include the estimated unadjusted incidence of myocarditis and/or pericarditis during the period 1 through 7 days following administration of the 2023-2024 Formula of mRNA COVID-19 vaccines in males 12 years through 24 years of age in the Warnings and Precautions section of the Package Insert and in the Patient Package Insert, operating under U.S. License Number 2256.

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 1, dated June 27, 2025, and Patient Package Insert submitted under the original submission, dated June 23, 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 June 27, 2025, and the Patient Package Insert submitted on June 23, 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.

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 an FDA Form 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)).

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.

We will include the information contained in the above-referenced supplement in your biologics license application file.

If you have any questions, please contact the (b) (6), (b) (6), by email (b) (6) @fda.hhs.gov).

Sincerely,

(b) (6)
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research