



Our STN: BL 125796/127

SUPPLEMENT APPROVAL

August 7, 2026

ModernaTx, Inc
Attention: Marco Pompei
325 Binney Street
Cambridge, MA 02142

Dear Mr. Pompei,

We have approved your request received on February 5, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Respiratory Syncytial Virus Vaccine (MRESVIA) to update the Package Insert with data from an interim analysis of Study mRNA-1365-P101 (Postmarketing Requirement #2 from the June 14, 2024, approval letter), to describe in Section 8.4 (Pediatric Use) the observed imbalance in severe and/or hospitalized RSV lower respiratory tract disease among participants who were vaccinated from 5 months through 7 months of age and RSV-seronegative at baseline.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 11, dated August 6, 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 6, 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.

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:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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.

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

Sincerely,

Andrea Hulse, M.D.
Acting Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research