U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125781/255

**SUPPLEMENT APPROVAL**
**PMC FULFILLED**
August 4, 2026

Sarepta Therapeutics, Inc.
Attention: Patrick O'Malley
215 First Street
Cambridge, MA 02142

Dear Patrick O'Malley:

We have approved your request received May 18, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for delandistrogene moxeparvovec-rokl (ELEVIDYS) to update the United States Prescribing Information (USPI) to include the FDA authorized test (approved (b) (4) under PMA (b) (4) ) to select patients for treatment with ELEVIDYS with anti-AAVrh74 total binding antibody titers <1:400 as requested under PMC #2 under BLA 125781/0.

## LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 3, dated August 3, 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. 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 125781/255 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.

## FULFILLED POSTMARKETING COMMITMENTS

This submission fulfills your postmarketing commitment #2 identified in the June 22, 2023, approval letter for STN BL 125781/0 for delandistrogene moxeparvovec-rokl (ELEVIDYS). The commitment addressed in this submission is as follows:

2. Sarepta commits to conducting adequate analytical and clinical validation testing to establish (b) (4) developed to accurately and reliably detect anti-AAVrh74 total binding antibodies that can be used to identify patients with DMD who may benefit from delandistrogene moxeparvovec-rokl therapy. The results of the validation study are intended to inform product labeling. The clinical validation should be supported by a clinical bridging study comparing the (b) (4) and the clinical trial enrollment assays.

   (b) (4)

We remind you that there is a PMR study titled, “A Long-term Multicenter Prospective Observational Study Evaluating the Comparative Effectiveness and Safety of Sarepta Gene Transfer Therapy vs. Standard of Care in Participants with Duchenne Muscular

Dystrophy under Conditions of Routine Clinical Practice – Safety PMR Cohort," under BL125781/189 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.

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

Sincerely,

Patroula Smpokou, MD
Director
Division of Clinical Evaluation General Medicine
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research