



Our STN: BL 125643/753

**SUPPLEMENT APPROVAL**

February 5, 2026

Kite Pharma, Inc.  
Attention: Arjana Pradhan, PhD  
2400 Broadway  
Santa Monica, CA 90404

Dear Dr. Pradhan:

We have approved your request received August 6, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for axicabtagene ciloleucel. The supplement revises United States Prescribing Information (USPI) as follows: Section 1 (Indication and Usage) removes the Limitations of Use for Primary Central Nervous System Lymphoma (PCNSL); Section 5 (Warnings and Precautions) adds neurological toxicities identified from the new clinical study; Section 6 (Adverse Reactions) incorporates study information and adverse reactions from the new clinical study; and Section 12.3 (Pharmacokinetics) adds pharmacokinetics data from the new clinical study.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: 04608487

## **LABELING**

We hereby approve the draft content of labeling the Package Insert submitted under amendment 11, dated February 4, 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 <https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources>. Content of labeling must be identical to the Package Insert submitted on February 4, 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 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/spl-standard-content-labeling-technical-qs>.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125643 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.

## **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.

Because the biological product for this indication has an orphan drug designation, you are exempt from this requirement.

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

Sincerely,

Bindu George, MD  
Acting Director  
Division of Clinical Evaluation Hematology  
Office of Clinical Evaluation  
Office of Therapeutic Products  
Center for Biologics Evaluation and Research