Our STN: BL 125643/733

SUPPLEMENT APPROVAL
October 21, 2025

Kite Pharma, Inc.
Attention: Solmaz Dehghan, PharmD, PhD
2400 Broadway
Santa Monica, CA 90404

Dear Dr. Dehghan:

We have approved your request received April 24, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for axicabtagene ciloleucel (axi-cel; Yescarta) to include an optional one-time short-term storage of Yescarta commercial product at - 80°C ± 10°C for a period of up to 90 days at authorized treatment centers (ATCs) and the product must be discarded after the product reaches its labeled expiration date of 12 months at ≤ − 150°C or 90 days at − 80°C, whichever occurs first.. Changes include updated carton/container labels and updated USPI section 16 How supplied/Storage and Handling.

LABELING

We hereby approve the draft content of labeling for the Package Insert submitted under amendment 3, dated October 9, 2025 and the draft carton and container labels submitted under amendment 3, dated October 9, 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 October 9, 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on October 9, 2025, 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 125643/0 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.

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

Sincerely,

Kimberly Schultz, PhD
Director
Division of Gene Therapy 2
Office of Gene Therapy
Office of Therapeutic Products
Center for Biologics Evaluation and Research