Our STN: BL 125643/793

SUPPLEMENT APPROVAL
June 15, 2026

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

Dear Dr. Solmaz Dehghan:

We have approved your request received December 19, 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) for long-term storage of Yescarta drug product at less than or equal to -120°C during the 12-month shelf-life period at authorized treatment centers (ATCs), with a single transfer allowed from vapor phase of liquid nitrogen (≤-150°C) to ≤-120°C mechanical freezer storage. Yescarta may be stored a single time at -80°C (+/- 10°C), for up to 90 days at ATCs, within the labeled expiration date, after ≤-120°C storage and cannot be returned back. Storage of Yescarta prior to shipment remains in the vapor phase of liquid nitrogen.
The revision of the Package Insert in section 16 HOW SUPPLIED/STORAGE AND HANDLING for the stated storage and transportation requirements.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 7, dated June 12, 2026, and the draft carton and container labels submitted under amendment 6, dated June 11, 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 June 12, 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.
CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on June 11, 2026, 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)).

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