



Our STN: BL 125787/443

SUPPLEMENT APPROVAL

June 15, 2026

Vertex Pharmaceuticals Inc
Attention: Brett Richardson
50 Northern Avenue
Boston, MA 02210

Dear Brett Richardson:

We have approved your request received December 15, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for exagamglogene autotemcel (exa-cel, CASGEVY™) to update the Chain of Identity (COI) 10-digit naming convention to align with the ISBT 128 ICCBAA 15-digit naming convention. The container (vial) label, carton label and syringe label revised to align with this 15-digit numbering format.

LABELING

We hereby approve the draft content of carton and container labels submitted under amendment 0, dated December 15, 2025.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on December 15, 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 BLA, STN BL 125787/0 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(s) 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