



Our STN: BL 125772/0

**PROPOSED SUFFIX**  
**ACCEPTABLE BUT NOT THE FIRST**  
November 14, 2022

CSL Behring LLC  
Attention: Poorva Chiddarwar  
1020 First Avenue  
P.O. Box 61501  
King of Prussia, PA 19406

Dear Ms. Chiddarwar:

Please refer to your Biologics License Application (BLA) received March 24, 2022, submitted under section 351(a) of the Public Health Service Act (PHS Act) for etranacogene dezaparvovec.

Reference is made to your request for review of proposed suffixes for etranacogene dezaparvovec. You provided 10 suffixes, in order of preference.

The Center for Biologics Evaluation and Research's Office of Tissues and Advanced Therapies and Office of Compliance and Biologics Quality have reviewed your proposed proper name suffixes, and we find your third proposed suffix, -drlb, conditionally acceptable for inclusion in your proper name. Should your 351(a) BLA be approved during this review cycle, etranacogene dezaparvovec-drlb will be the proper name designated in the license, and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your proposed proper name unacceptable upon our re-evaluation at that time, we will inform you of our finding.

The proposed suffixes were evaluated using the criteria set forth in Guidance for Industry Nonproprietary Naming of Biological Products (<https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>). A suffix should be unique, devoid of meaning, composed of four lowercase letters of which at least three are distinct, nonproprietary, and free of legal barriers that would restrict its usage. A suffix should not include numbers or symbols, be false or misleading with respect to safety or efficacy of the product, include abbreviations commonly used in clinical practice in a manner that may lead it to be misinterpreted as another element on the prescription or order, contain or suggest a drug substance name or core name, look similar to or have the potential to be mistaken for the name of a currently marketed product, connote the name of the license holder, or be too similar to another FDA-

designated suffix. Using the above criteria, your proposed suffixes are not devoid of meaning and thus were found unacceptable for the following reasons:

- Connotes the product proper name etranacogene dezaparvovec and the viral vector, adeno-associated virus: -eaav
- Connotes the indication of the product, control hemophilia B bleeding rate: -cbbv

If you have any questions, please contact the Regulatory Project Manager, Shalini Seetharaman, at (240) 672-8158 or by email at [Shalini.Seetharaman@fda.hhs.gov](mailto:Shalini.Seetharaman@fda.hhs.gov).

Sincerely,

Ramani Sista, PhD  
Director  
Division of Regulatory Project Management  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research