



Our STN: BL 125722/0

PROPRIETARY NAME UNACCEPTABLE

June 12, 2024

PTC Therapeutics, Inc.
Attention: Agnes Cobbum, MS
100 Corporate Court
South Plainfield, NJ 07080

Dear Agnes Cobbum:

Please refer to your Biologics License Application (BLA) received March 15, 2024, submitted under section 351(a) of the Public Health Service Act for eladocagene exuparvovec, requesting a proprietary name review for UPSTAZA.

In consultation with CBER's Advertising and Promotional Labeling Branch, we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, **UPSTAZA**, is **UNACCEPTABLE**.

The proposed name, **UPSTAZA**, may cause medication errors due to the potential phonetic and orthographic confusion with highly similar product names.

You may submit a new proprietary name for our consideration. Any proposed proprietary name(s) should comply with the regulations regarding false, misleading, or fanciful names, and regarding phonetic or orthographic similarities to other medicinal products.

If you require additional information on developing proprietary names for drugs, we refer you to the following draft guidance for industry *Best Practices in Developing Proprietary Names for Drugs* at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM398997.pdf>, and guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names* at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068>.

If you have any questions, please contact the Regulatory Project Manager, Tolani Ishola at (240) 858-2819 or by email at tolani.ishola@fda.hhs.gov.

Sincerely,

Beatrice Kallungal, MS
Director
Division of Review Management and Regulatory Review 1
Office of Review Management and Regulatory Review
Office of Therapeutic Products
Center for Biologics Evaluation and Research