



Our STN: BL 125722/0

PROPRIETARY NAME ACCEPTABLE

October 7, 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 July 29, 2024, submitted under section 351(a) of the Public Health Service Act for eladocogene exuparvovec, requesting a proprietary name review for KEBILIDI.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, KEBILIDI is acceptable.

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