



Our STN: BL 125610/0

PROPRIETARY NAME ACCEPTABLE

August 10, 2017

Spark Therapeutics, Inc.
Attention: Jim Wang, Ph.D.
3737 Market Street, Suite 1300
Philadelphia, PA 19104

Dear Dr. Wang:

We have reviewed your May 16, 2017, submission to your Biologics License Application (BLA) for voretigene neparvovec, requesting a proprietary name review for LUXTURNA.

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, LUXTURNA is Acceptable.

If you have any questions, please contact the Regulatory Project Manager, Nevitt Morris at (240) 402-8269.

Sincerely yours,

Ramani Sista, Ph.D., R.A.C.
Director
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research