



Our STN: BL 125591/0

PROPRIETARY NAME ACCEPTANCE

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406

Dear Mr. White:

We have reviewed your submission dated May 29, 2015 to your biologics license application (BLA) for Antihemophilic Factor (Recombinant), Single Chain, requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB), we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your alternative proposed proprietary name, **AFSTYLA**, is acceptable at this time.

The primary proposed proprietary name, **(b) (4)**, is unacceptable because it implies that the product has a unique composition and effectiveness beyond that supported by the data.

If you have any questions, please contact LT Thomas J. Maruna, USPHS, MSc, MLS(ASCP) at (240) 402-8454.

Sincerely,

Paul D. Mintz, MD
Director
Division of Hematology Clinical Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research