



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