



Our STN: BL 125566/0

**PROPRIETARY NAME ACCEPTANCE**

Attention: Mr. Erik Bjornson  
Baxter Healthcare Corporation  
One Baxter Way  
Westlake Village, CA 91362

Dear Mr. Bjornson:

We have reviewed your submission dated November 25, 2014 to your biologics license application (BLA) for Antihemophilic Factor (Recombinant), PEGylated requesting a proprietary name review.

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 primary proprietary name, ADVALTIS, is unacceptable. Your proposed alternative proprietary name, ADYNOVATE, is acceptable.

Your proposed primary name, ADVALTIS, is unacceptable because it might be confused with other medicinal products with orthographic or phonological similarities.

If you have any questions, please contact Edward Thompson at (240) 402-8443.

Sincerely,

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