



Our STN: BL 125566/0

**PROPRIETARY NAME NON-ACCEPTANCE**

Baxter Healthcare Corporation  
Attention: Mr. Erik Bjornson  
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 proprietary names, (b) (4) (primary name) and ADVATE PRO (alternative name), are unacceptable.

The proposed primary name, (b) (4) is considered to be fanciful because it looks and sounds like "advantage" or "advanced state." Therefore, this name may suggest superior effectiveness over other products, when such has not been supported by the data.

The proposed alternative name, ADVATE PRO, is considered to be fanciful because the modifier "PRO," often used to mean "professional." Therefore, it may imply superiority and minimize the current version of the product as inferior, when such has not been supported by the data.

You may submit a new proprietary name for FDA consideration. Any alternative proprietary name(s) should comply with the regulations regarding false, misleading or fanciful names and should not 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,

Basil Golding, MD  
Director  
Division of Hematology Research and Review  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research