



Our STN: BL 125574/0

**PROPRIETARY NAME ACCEPTANCE**

Bayer HealthCare LLC  
Attention: Ms. Vicki Chen  
100 Bayer Boulevard  
PO Box 915  
Whippany, NJ 07981-09115

Dear Ms. Chen:

We have reviewed your submission dated December 16, 2014 to your biologics license application (BLA) for Antihemophilic Factor (Recombinant) 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 name, KOVALTRY, is acceptable.

If you have any questions, please contact the Regulatory Project Manager, Pratibha Rana, at [pratibha.rana@fda.hhs.gov](mailto:pratibha.rana@fda.hhs.gov) or (240) 402-4833.

Sincerely yours,

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