



Our STN: BL 125661\0

**PROPRIETARY NAME ACCEPTABLE**

October 13, 2017

Michelle Meng, MD  
Bayer Healthcare, Inc.  
100 Bayer Boulevard  
Whippany, NJ 07981

Dear Dr. Meng:

We have reviewed your August 30, 2017, submission to your Biologics License Application (BLA) for Antihemophilic Factor (Recombinant), PEGylated, requesting a proprietary name review for JIVI.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, JIVI is Acceptable.

If you have any questions, please contact the Regulatory Project Manager, Candace Jarvis at (240) 402-8315.

Sincerely yours,

Ramani Sista, PhD, RAC, CQA  
Director  
Division of Regulatory Project Management  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research