



Our STN: BL 125671

**PROPRIETARY NAME ACCEPTABLE**

Novo Nordisk, Inc.  
Attention: Ms. Barbara Davies  
P.O. Box 846  
Plainsboro, NJ 08536

April 09, 2018

Dear Ms. Davies:

We have reviewed your February 27, 2018, submission to your Biologics License Application (BLA) for Antihemophilic Factor (Recombinant), GlycoPEGylated, requesting a proprietary name review for ESPEROCT.

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, ESPEROCT is Acceptable.

If you have any questions, please contact the Regulatory Project Manager, Jean Dehdashti, at (240) 402-9146.

Sincerely,

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