



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