



Our STN: BL 125611/0

PROPRIETARY NAME ACCEPTABLE

Novo Nordisk Inc.
Attention: Ms. Patricia D Wilson
PO Box 846
Plainsboro, NJ 08536

Dear Ms. Wilson:

We have reviewed your September 1, 2016, submission to your Biologics License Application (BLA) for Coagulation Factor IX (Recombinant), GlycoPEGylated, requesting a proprietary name review for REBINYN.

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, REBINYN is Acceptable.

If you have any questions, please contact the Regulatory Project Manager, 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