



Our STN: 125398/0

Novo Nordisk Inc.
Attention: Lewis Pollack, PhD
P.O. Box 846
Plainsboro, NJ 08536

Dear Dr. Pollack:

We have reviewed your amendment to your biologics license application (BLA) for Coagulation Factor XIII A Subunit (Recombinant) dated November 19, 2013, requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, TRETEN, is acceptable at this time.

If you have any questions, please contact the Regulatory Project Manager, Dr. Jiahua Qian, at (301) 827-6156.

Sincerely yours,

Basil Golding, MD
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research