



Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Our STN: BL 125398/0

Novo Nordisk Inc.
Attention: Mr. Robert Fisher
100 College Road West
Princeton, NJ 08540

Dear Mr. Fisher:

We have reviewed your amendment dated May 16, 2013 to your biologics license application (BLA) for Coagulation Factor XIII A Subunit (Recombinant), requesting a change of the proprietary name for Coagulation Factor XIII A Subunit (Recombinant) from “NovoThirteen” to “Novothirteen”.

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, Novothirteen, 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