



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