



Our STN: BL 125398/0

Novo Nordisk Inc.
Attention: Mary Ann McElligott, Ph.D.
100 College Road West
Princeton, NJ 08540

Dear Dr. McElligott:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated February 23, 2011 for Coagulation Factor XIII A Subunit (Recombinant) to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review goal date is December 23, 2011. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

We will contact you regarding your proposed labeling no later than November 24, 2011. If post marketing study commitments (506B) are required, we will contact you no later than November 24, 2011.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Manager, Debbie Cordaro, at (301)-827-6157.

Sincerely yours,

Alan E. Williams, Ph.D.
Associate Director for Regulatory Affairs
Acting Chief, Regulatory Project
Management Branch
Office of Blood Research and Review
Center for Biologics
Evaluation and Research