



Our STN: BL 125398/0

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

Dear Mr. Fischer:

This letter is in regard to your biologics license application (BLA) for Coagulation Factor XIII A Subunit (Recombinant), manufactured at your Bagsvaerd (b) (4) locations, submitted under section 351 of the Public Health Service Act (42 U.S.C. 262).

We have completed our review of all the submissions you have made relating to this BLA. We are unable to complete the final approval action pending review of the (b) (4), inspection of your facility located at (b) (4), and because of the deficiency outlined below.

1. You have not demonstrated that you have an acceptable, validated 100% Visual Inspection Program for Coagulation Factor XIII A Subunit (Recombinant). Please provide the following:
  - a. The 100% visual inspection validation protocol, and study final results, using your updated visual inspection test defect kit. Please include validation of AQL/LQ testing as well.
  - b. Acceptance limits for each of the defect categories (critical, major, and minor sub groupings, as appropriate for your product).

We stopped the review clock with the issuance of this letter. We will reset and start the review clock when we receive your complete response.

Within 10 days after the date of this letter, you should take one of the following actions: (1) amend the application; (2) notify us of your intent to file an amendment; or (3) withdraw the application.

You may request a meeting or teleconference with us to discuss the steps necessary for approval. For PDUFA products, please submit your meeting request as described in our "Guidance for Industry: Formal Meetings with Sponsors and Applicants for PDUFA Products," dated February 2000. This document is available on the internet at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079744.pdf> or may be requested from the Office of Communication, Outreach, and Development, at (301) 827-1800. For non-PDUFA products, please contact the regulatory project manager. For details, please also follow the instructions described in CBER's SOPP 8101.1: Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants. This document also is available on the internet at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079448.htm>, or may be requested from the Office of Communication, Outreach, and Development.

Please be advised that, as stated in 21 CFR 601.3(c), if we do not receive your complete response within one year of the date of this letter, we may consider your failure to resubmit to be a request to withdraw the application. Reasonable requests for an extension of time in which to resubmit will be granted. However, failure to resubmit the application within the extended time period may also be considered a request for withdrawal of the application

If you have any questions regarding the above, 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