



Our STN: BL 125611/0

BLA FILING NOTIFICATION

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
P.O. Box 846
Plainsboro, NJ 08536

Dear Ms. Wilson:

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 May 16, 2016, for Coagulation Factor IX (Recombinant), GlycoPEGylated to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review classification for this application is Standard. Therefore, the review goal date is June 3, 2017. 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 are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which include the timeframes for FDA internal milestone meetings. We plan to hold our internal mid-cycle review meeting on November 10, 2016. Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process.

We will contact you regarding your proposed labeling no later than May 4, 2017. If post marketing study commitments (506B) are required, we will contact you no later than May 4, 2017.

At this time, we are still assessing if we will be discussing this application at an Advisory Committee meeting. We expect to notify you of a decision shortly.

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, Edward Thompson, at (240) 402-8443.

Sincerely,

Iliana Valencia, MS
Chief
Regulatory Project Management Branch
Office of Blood Research and Review
Center for Biologics Evaluation and Research