



Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
October 11, 2016
Sent by email

Dear Ms. Wilson:

We are reviewing your May 16, 2016 biologics license application for Coagulation Factor IX (Recombinant), GlycoPEGylated. We have reviewed the information and associated certificates of analysis provided with your samples for testing on 6 September 2016, as part of your submission under STN 125611/0.9 and have the following comments and request for additional information:

FIX OSCA (One Stage Clotting Assay (M056))

1. The aPTT reagent, SynthAFax is not available for distribution in the US. Please provide us one box of the SynthAFax kit, comprised of both aPTT reagent and Calcium Chloride to allow testing of your product. Please send the reagent to:

Grainne Tobin
LACBRP/ DBSQC/ OCBQ
US Food and Drug Administration
10903 New Hampshire Avenue
WO75-G634
Silver Spring, MD 20993

2. You state that the current control is a diluted sample of nonacog beta pegol drug product batch (b) (4), but provided the Certificate of Analysis for the Control batch (b) (4) as Appendix D. Please provide the potency of the diluted sample you sent us as control.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response and your notification of the shipment for this request as an amendment to this file by October 31, 2016 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is June 3, 2017.

Please send an acknowledgement message for receipt of this request.

If you have any questions, please contact me at (240) 402-8443.

Sincerely,
Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR