

Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
May 30, 2017
Sent by email

Dear Ms. Wilson:

We are reviewing your May 16, 2016 biologics license application for Coagulation Factor IX (Recombinant), GlycoPEGylated. We determined that the following revisions to your package insert label are necessary to continue our review:

1. We have made two changes to the text in section 6.3 (p. 8), and section 13.2 (p. 11). Please accept.
2. We found few places where spaces were needed or should be deleted (please see track changes) and please consider adding page numbers to the PI.

The review of this application is on-going and issues may be added, expanded upon, or modified.

Please submit your response for this request as an amendment to this file by May 30, 2017, referencing the date of this request. Please include **both a red-line strike out and clean copy versions** of the revised package insert in WORD format. 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/OTAT/DRPM

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Thank you.