

Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
May 25, 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 labels are necessary to continue our review:

1. Thank you for making many of the requested changes.
2. We agree to retain some of the original text as you have provided an adequate response.
However, there are few issues where we do not concur with the deletions or the new language proposed by you. Please adhere to the text in the attached version.
3. Please submit by May 26, at 8 am Eastern Time the revised PI, a clean copy as well as a track changed copy.

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 26, 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.