



Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
March 24, 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 information is necessary to continue our review:

Based on the exposure data in Response to FDA Information Request received 12/15/2016 in Table 1-Individual Duration of Exposure to Rebinyn and Table 7-1 in the Advisory Committee Briefing Document, please provide an updated table with the subject ID numbers for the exposure data. Please provide data from the main phase and extension study for Trial 3774, as the ongoing part of the study has not been evaluated by the FDA.

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 March 28, 2017, 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/OTAT/DRPM