

Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
November 22, 2016
Sent by email

Dear Ms. Wilson:

We are reviewing your May 16, 2016 biologics license application for Coagulation Factor IX (Recombinant), GlycoPEGylated. We are providing the following comments and request for additional statistical information to continue our review:

Please provide details on which data set was used to generate the following tables in your report. Please specify which is the response variable used to generate the table, and which other variables were used to include/exclude any observations from the data. In addition, you may also provide the program code to generate those tables (please also provide detailed read me file if any program code is submitted)

In report-body for study 3774:

Table 11–2 Annualised bleeding rate - full analysis set
Table 11–7 Haemostatic response - full analysis set
Table 14.2.4 Number of injections of nonacog beta pegol per bleed - full analysis set

In report-body for study 3747:

Table 11–5 Annualised bleeding rate – full analysis set
Table 11–3 Haemostatic response and success rate – full analysis set
Table 11–8 Number of injections of nonacog beta pegol per bleeding episode – full analysis set

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 November 25, 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/OTAT/DRPM

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Thank you.