

Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
January 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 are providing the following comments and request for additional information to continue our review:

1. The Study Report No. NN212513 titled “26 Week Toxicity Study by Intravenous Administration to Rowett Nude Rats (b) (4) Followed by a 26 Week Treatment Free Period (GLP)” indicates that cerebrospinal fluid (CSF) was collected during the study. Please provide the results of these analyses and your interpretation of the data.
2. In the Study Report No. 209294 titled “40 K Polyethyleneglycol (PEG) Exploratory Toxicity Study by Intravenous (bolus) Administration on Alternate Days to (b) (4) Wistar Rats for 2 or 6 Weeks” it is states that “samples (wax blocks and slides) of the brain (choroid plexus) from the Main study and Satellite animals were dispatched to the Sponsors pathologist for supplementary processing. Results from any supplementary processing is reported separately and not as part of this study.” However, no additional reference to data from the supplementary processing was submitted. Please provide the data from the supplementary processing. If these data are not available, please provide an explanation for their omission.

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 February 9, 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

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Thank you