

Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
November 1, 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 information on your (b) (4) control to continue our review:

CBER lab has conducted an investigation of the control sample vials provided for the (b) (4) test. The (b) (4) of the control vial used for the information request dated Oct. 20, 2016 was found to be (b) (4). A new vial of control was (b) (4) and tested to have (b) (4). The (b) (4) results obtained from the second vial show that it has consistent results of protein concentration of (b) (4) and the (b) (4) of (b) (4) from (b) (4) injections.

Thus, the results from the second vial are within the acceptance criteria. However, we are concerned with the vial-to-vial variation of (b) (4). We suggest you implement appropriate precautionary steps to prevent potential vial-to-vial variation of (b) (4) since the control is so (b) (4) sensitive. We also suggest that you revise your SOP to include steps to verify (b) (4) of the control before use.

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 14, 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