

Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
October 11, 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 to continue our review:

Analytical Procedure (b) (4) “Protein Content and (b) (4)”

As per document (b) (4) a new (b) (4) was conditioned in CBER lab with (b) (4)

(b) (4) We found that the percent of (b) (4) in the control was progressively increasing with injections, (b) (4) respectively. (b) (4) subsequent injections of the control were made and the (b) (4) were (b) (4) All results are significantly higher than the established range of (b) (4) per your document entitled “Response to FDA Information Request, dated Sep. 05, 2016”.

Additionally we observed the following trends: (b) (4)

GlycoPEGylated rFIX intermediate and the control samples were stored at (b) (4) upon receiving them and the samples were (b) (4) before use, per your instructions in document entitled “Response to FDA Information Request, dated Sep. 29, 2016”. The (b) (4) for the (b) (4) during the run.

Please clarify why the control sample contains significant higher (b) (4) than your established limits of (b) (4)

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 2, 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