



Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
May 10, 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 request to continue our review:

Please submit a proposed range for your (b) (4) specification to replace your open ended specification of (b) (4).

The review of this submission is on-going and issues may be added, expanded upon, or modified.

Please submit your response and your notification of the shipment for this request as an amendment to this file by May 12, 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