



Our Reference: BLA 125611/0

Novo Nordisk Inc.  
Attention: Ms. Patricia D. Wilson  
May 4, 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 for the Potency by One-Stage Clotting Assay, M056 review:

In your response to the Information Request question 1d, provided in Amendment 23, received 13 December 2016 (Section 2.1.8), you provided data demonstrating linearity and parallelism of your method by comparing the upper and lower asymptotes and the slope ratios between test sample and standard. Please include these acceptance criteria for a valid assay in your SOP. Please note, this is the only acceptable way in which you have shown linearity and parallelism of your assay. Please submit your updated SOP.

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 11, 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