

Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
May 18, 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 Amendment 51 submitted on 11 May 2017 for the Potency by One-Stage Clotting Assay, M056:

1. The acceptance criteria for ratio of slopes (sample/reference) of (b) (4) you have added to your SOP, M056, version 1.0., date 10 May 2017, in Amendment 51 is not acceptable as it is too wide. Furthermore, it does not match the validation results you provided in section 2.1.8 of Amendment 23 (between (b) (4)). Please amend your acceptance criteria to reflect the results you obtained in your validation study. The acceptance criteria of (b) (4) for slope ratio is commonly used, consistent with your method validation results, and is acceptable in this instance.
2. In the validation results provided in section 2.1.8 of Amendment 23, you provided ratios of upper and lower asymptotes of sample to standard, however the acceptance criteria in your amended SOP, M056, is the difference of upper and lower asymptotes (sample/reference). Please explain how the acceptance criteria in your amended SOP are calculated and why you are using criteria that are different from the results you provided in your validation study. Please amend your SOP with acceptance criteria that matches your validation results. Please provide your updated SOP by 26 May 2017.

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 24, 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