



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our Reference: STN 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
August 12, 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:

Reference: The analytical procedures of (b) (4) "Identity, PEG Profile and Product Related Impurities by (b) (4) and (b) (4) "Protein Content and (b) (4)

1. For (b) (4)
 - a. The total volume for DP 2000 IU sample after reconstitution is (b) (4), which is different from the volume of (b) (4) used for the calculation of protein content in unit of mg/mL. Please clarify whether a conversion is needed for the protein content calculation of a DP 2000 IU sample and revise the section 10.3.2 of your SOP accordingly.
2. For (b) (4)
 - a. Please clarify whether (b) (4) is used for a typical DP chromatogram. If the answer is yes, please provide details of such integration with necessary zoomed-in figures.
 - b. Please provide a zoomed-in chromatogram to clearly show the peak split between tri-(b) (4)
 - c. Please provide the range of "X" for the (b) (4) in the section of 10.2.

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 to this information request as an amendment to this file by August 26, 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/OBRR