



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
September 23, 2016
Sent by email

Dear Ms. Wilson:

We are reviewing your May 16, 2016 biologics license application for Coagulation Factor IX (Recombinant), GlycoPEGylated. We request following information to perform 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. You provided one vial of rFIX intermediate (Batch (b) (4)) as column conditioning material for (b) (4) without a COA or protein concentration. Please provide the protein concentration and describe the handling procedure, including how many of (b) (4) is allowed for this material. If the material cannot be (b) (4) , please send us two more vials of this material to:

Al Del Grosso
Food and Drug Administration
Center for Biological Evaluation and Research
Division of Biological Standards and Quality Control
10903 New Hampshire Avenue
WO75, G-717
Silver Spring, MD 20993-0002

2. The N9GP control standard (batch (b) (4) for both (b) (4) was received without any companion document. Please provide your established limits of (b) (4) and protein concentration as per (b) (4) and percentage values of rFIX, mono-PEG rFIX, (b) (4) and total impurities as per (b) (4) in order to evaluate the system suitability of both assays.

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 September 30, 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