



Our Reference: BLA STN 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
August 18, 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:

Sample and reagent for in-support testing

1. Please provide 2 lots of each 500 IU and 2000 IU, including Certificate of Analysis (CoA) /batch release results for the lots submitted.
2. Reagents for test methods:
 - a. FIX OSCA
 - i. 3 vials per lot
 - ii. Reference standard and control: sufficient for two independent tests
 - iii. Histidine solution (diluent): sufficient for reconstitution of all samples submitted for testing.
 - iv. Please provide the associated CoAs
 - b. (b) (4)
 - i. 3 vials per lot
 - ii. Coagulation Factor IX (Recombinant), glycoPEGylated (rFIX) intermediate with a COA or protein concentration of at least (b) (4), preferably in 3 different vials
 - iii. Reference material with the protein concentration (total protein at least (b) (4) preferably in 3 different vials)

- iv. Control with a COA or protein concentration of at least 500 µg, preferably in 3 different vials
- c. (b) (4)
 - i. 3 vials per lot
 - ii. Reference material with the protein concentration (total protein of at least (b) (4) preferably in 3 different vials)
 - iii. Control with a COA (total protein of at least (b) (4), preferably in 3 different vials)

3. Please ship the samples and reagents 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

Contact Al Del Grosso at 240-402-9470 (alfred.del-grosso@fda.hhs.gov) or Marie Anderson at 240-402-6292 (marie.anderson@fda.hhs.gov) for questions on the shipment.

Please send these samples, reagents and documentation by September 1, 2016 or notify CBER by this date of when the shipment can be expected.

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 notification of the shipment for this request as an amendment to this file by September 1, 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

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Thank you