



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our Reference: BLA STN 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
September 9, 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:

Endotoxin

1. Please provide the potency strengths (i.e., 500, 1000 or 2000 IU/vial) of drug product lots (numbers: (b) (4)) used in preliminary interference screening studies listed in information request response dated August 1, 2016.
2. Please provide product positive control spike concentration used in endotoxin inhibition and enhancement test of histidine solution by (b) (4) .
3. According to section 3.2.P.5.4 for histidine solution, endotoxin specification is (b) (4) . However, specification of (b) (4) was used in calculation of maximum valid dilution and inhibition and enhancement test by (b) (4) . Please clarify the discrepancy.

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 22, 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