



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
June 7, 2016
Sent by email

Dear Ms. Wilson:

We are reviewing your May 16, 2016 biologics license application for Coagulation Factor IX (Recombinant), GlycoPEGylated. We determined that the following information is necessary to continue our review:

1. Are any of the processes and equipment with regards to STN 125611.0 new or novel to your facility?
2. Are licensed US products currently manufactured in/on any rooms/areas, equipment or manufacturing lines in this submission?
3. In a tabular format, please indicate the site, building, rooms or areas, and process steps which are shared amongst licensed US products (please indicate the licensed US product(s)). Please cross-correlate the steps to your process flow in the submission.
4. Are any of your bioreactors in these areas used for either mammalian and bacterial cell lines? If this is the case, please indicate within the submission justification for this use with regards to risk mitigation.

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 June 21, 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/RPMS

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Thank you.