



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  
July 22, 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:

Please submit a revised pharmacovigilance plan so that it reflects your assessment of identified or potential risks from chronic exposure to a pegylated product, and possible accumulation of polyethylene glycol (PEG) in the body.

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 5, 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