

Our Reference: BLA 125611/0

Novo Nordisk Inc.  
Attention: Ms. Patricia D. Wilson  
December 30, 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:

1. Please ensure all Case Report Forms (CRFs) were submitted to the BLA.
2. Please provide the following missing CRFs: Subject (b) (6)
3. Please provide the source documents for Subject (b) (6)
4. In an IR response dated December 15th 2016, you state that for the Pediatric Study -3774 “all patients on prophylaxis were treated with fixed once weekly doses.” Please provide details on all pediatric subjects who received any additional doses for breakthrough bleeding including spontaneous, traumatic, or joint bleeds.
5. For all subjects who received REBINYN, please provide a table which summarizes:
  - a. calculated renal clearance based on 1) BUN 2)Cr
  - b. % change in Creatinine Clearance (Cr Cl) from baseline to final study visit
  - c. total dose of REBINYN received at the time of the final study visit when the Cr Cl was documented
  - d. total # of doses REBINYN administered until this Cr Cl was calculated  
For any missing data for dose, please highlight those values and provide an explanation as to the period for which information is missing
  - e. Urinalysis summary ( normal or abnormal) with descriptive text of the urinalysis abnormality for all subjects.

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 for this request as an amendment to this file by January 13, 2017, 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/OTAT/DRPM