

Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
November 29, 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:

Per Section 505b(a)(2) of the Pediatric Research Equity Act, you are required to submit a pediatric assessment that contains data to support the safety and efficacy in pediatric subjects:

Under PREA, the pediatric assessment should contain data gathered from pediatric studies using appropriate formulations for each age group for which the assessment is required, and other data that are adequate to:

- Assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations
 - Support dosing and administration for each pediatric subpopulation for which the drug or the biological product has been assessed to be safe and effective
1. For each of the following age groups please provide a brief assessment (5-10 pages total) of the data gathered to support the safety and efficacy of this product in the pediatric population:
 - a. 0 to <2 years,
 - b. ≥2 years to <6 years,
 - c. ≥6 years to <12 years,
 - d. ≥12 years to <16 years of age

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 and your notification of the shipment for this request as an amendment to this file by December 12, 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/OTAT/DRPM