



Our Reference: BLA 125611/0

Novo Nordisk Inc.
Attention: Ms. Patricia D. Wilson
February 3, 2017
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 comment and request for additional information to continue our review:

The Summary of Clinical Efficacy states 14 subjects were diagnosed with moderate Hemophilia B. Please identify these subjects and their corresponding trial number. Please also conduct a sensitivity analysis for ABR (overall, spontaneous, traumatic), excluding those subjects with moderate Hemophilia B.

The review of this application is on-going and issues may be added, expanded upon, or modified.

Please submit your response for this request as an amendment to this file by February 9, 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