

Our Reference: BLA 125611/0

Novo Nordisk Inc.  
Attention: Ms. Patricia D. Wilson  
May 19, 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 request to continue our review:

In section 3.2.S.2.2 Filling, Storage and Transportation, you stated:

*"Before transportation, the containers are (b) (4)*

*The transport will take place at (b) (4)*

Please provide data to support the stability of the product at (b) (4).

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

Please submit your response and your notification of the shipment for this request as an amendment to this file by May 23, 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

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Thank you