



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

Our Reference: BL 125566/0

Baxter Healthcare Corporation  
Attention: Mr. Erik Bjornson  
August 19, 2015  
Sent by email

Dear Mr. Bjornson:

We are reviewing your November 25, 2014 biologics license application (BLA) for Antihemophilic Factor (Recombinant), PEGylated. We are providing the following comment and request for additional information to continue our review:

1. In your amendment dated 13 August 2015, you did not provide the updated stability data on the conformance batches of Antihemophilic Factor (Recombinant), PEGylated bulk drug substance (BDS) (b) (4) under (b) (4) storage conditions, which you had committed to submit in the original BLA under STN 125566/0 and amendment dated 16 June 2015. Please provide these stability data to support the shelf-life of the BDS of Antihemophilic Factor (Recombinant), PEGylated.

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 27, 2015 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 November 25, 2015.

Please send an acknowledgement 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/RPMS

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Thank you