



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
September 4, 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 comments and request for additional information to continue our review:

1. Please submit the most recent certificate of GMP from the (b) (4) facility in (b) (4) (FEI (b) (4)).
2. Regarding the qualification of Suite (b) (4), please provide the locations that were chosen for environmental monitoring during the EMPQ (including identifying them on a map if possible), a description of how these locations were chosen, and which of these locations are monitored during routine environmental monitoring.

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 September 11, 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