

**From:** Thompson, Edward  
**Sent:** Friday, May 29, 2015 8:11 AM  
**To:** 'Erik Bjornson (Erik\_Bjornson@baxter.com)'  
**Cc:** Do, Yu (Yu.Do@fda.hhs.gov)  
**Subject:** Information Request for BL 125566/0

**Contacts:** Erik Bjornson - Baxter Healthcare Corporation

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 provide the data sets and the related program code for the analyses of following endpoints of study 261201.
2. Please also provide a readme file explaining each of the documents submitted:
  - a. Rate of success of BAX 855 for treatment of bleeding episodes
  - b. Number of BAX 855 infusions needed for the treatment of bleeding episodes
  - c. Time intervals between bleeding episodes
  - d. Immunogenicity: Inhibitory antibodies to FVIII, binding antibodies to FVIII, BAX 855, and PEG, and anti-CHO antibodies



~~125566 BL 12~~

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 June 4, 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/PPMS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

Our Reference: BL 125566/0

Baxter Healthcare Corporation  
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May 29, 2015  
Sent by email

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