

From: Do, Yu
Sent: Tuesday, July 14, 2015 2:10 PM
To: Erik.Bjornson@baxalta.com
Cc: 'tung.koh@baxalta.com'; Thompson, Edward
Subject: Information Request: Response Due by Thursday, July 23, 2015 - Original
BLA 125566/0, Antihemophilic Factor (Recombinant), PEGylated

Dear Mr. Bjornson:

We are reviewing your original November 25, 2014 submission to BLA 125566/0 for Antihemophilic Factor (Recombinant), PEGylated. We determined that the following information is necessary to continue our review:

1. Please revise the specification for the degree of PEGylation for (b) (4) the drug product of Antihemophilic Factor (Recombinant), PEGylated, based on a statistical analysis of all available batches or lots produced in the proposed commercial manufacturing process.

The review of this submission is ongoing and issues may be added, expanded upon, or modified as we continue to review this submission. Please submit your response as an amendment to this file by July 23, 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 acknowledge receipt of this request and contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov if you have any questions.

Sincerely,

Yu Do, M.S.
Regulatory Project Manager
FDA/OMPT/CBER/OBRR/IOD/RPMS
(240) 402-8343
yu.do@fda.hhs.gov

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