

From: Do, Yu
Sent: Friday, June 12, 2015 11:22 AM
To: Erik.Bjornson@baxalta.com
Cc: Thompson, Edward
Subject: Information Request: Response Due by June 24, 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. In the original BLA under STN 125566/0, you did not include complete information about your control strategy. Please list all in-process controls and their limits/acceptance criteria in the manufacture of BAX855 bulk drug substance and drug product starting from the step of (b) (4) Chromatography. The request for this information is in accordance with the recommendations of Guidance for Industry, Q11 Development and Manufacture of Drug Substances.

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 Wednesday, June 24, 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.

The action due date for this file is November 25, 2015.

If you have any questions, please contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov.

Sincerely,

Yu Do, M.S.
Regulatory Project Manager
FDA/OMPT/CBER/OBRR/IOD/RPMS
(240) 402-8343
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