

From: Do, Yu
Sent: Thursday, May 21, 2015 8:21 AM
To: 'Erik.Bjornson@baxalta.com'
Cc: Thompson, Edward
Subject: Information Request: Response Due by June 16, 2015 - Original BLA 125566/0, BAX855, Anti-hemophilic Factor (Recombinant), PEGylated

Dear Mr. Bjornson:

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

1. Please submit updated stability data on the conformance batches of BAX855 bulk drug substance (b) (4) for (b) (4) storage conditions.
2. The submission did not include the test results of Free PEG, Total PEG and Degree of PEGylation on the conformance lots of BAX855 final drug product (FDP). Please take these parameters into account in the ongoing stability studies of the conformance lots of BAX855 FDP, and include the test results of these parameters when you submit updated stability data.
3. Please provide an assessment of the levels of murine IgG/PEGylated murine IgG in BAX855 (b) (4).

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 Tuesday, June 16, 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 you have any questions, please contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov.

Sincerely,

Yu Do, M.S.
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