

From: Do, Yu
Sent: Friday, July 17, 2015 11:04 AM
To: Erik.Bjornson@baxalta.com
Cc: Thompson, Edward
Subject: Information Request: Response Due by Monday, August 10, 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 are providing the following comments and request for additional information to continue our review:

With reference to your 16 July 2015 response to FDA Question 1b dated 30 June 2015, we take exception to the way you calculated the recoveries of total PEG.

Table 1 of validation protocol (b) (4)-65-09180 demonstrates that the specificity samples were prepared by (b) (4)

(b) (4). However, the calculation scheme you presented does not reflect that. To account for the (b) (4) in the specificity sample, an adjustment needs to be made.

In your example, the calculation for (b) (4) Total PEG is as follows:

(b) (4)

However, the (b) (4)

(b) (4) Total PEG should be:

(b) (4)

If our understanding of your sample preparation is correct, please recalculate the data in Appendices 2 and 3 and reevaluate the method performance in the validation report.

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 August 10, 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
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