

From: Do, Yu
Sent: Friday, July 10, 2015 5:13 PM
To: Erik.Bjornson@baxalta.com
Cc: tung.koh@baxalta.com; Thompson, Edward
Subject: Information Request: Response Due by July 15, 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. We are unable to verify your Point estimates for the mean ABR with 95% CI for the FAS, as well as its related subgroup analyses calculation (listed in your final study report on pages 85 and 86 of 809: e.g., 4.3 [3.4; 5.5] for prophylaxis arm and 43.4 [25.2; 74.8] for on-demand arm). We are using "aval" variable with "paramn"=3 in the submitted data file adhemeff.xpt for our calculation.

Please submit your SAS code and the data file (if it is different from the one that we use) for the calculation of the ABR for FAS, and a separate SAS code for the calculation of the subgroup ABR for FAS. Please make sure that your code and data set can regenerate the numbers in your 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 Wednesday, July 15, 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
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