

From: Do, Yu
Sent: Tuesday, September 22, 2015 8:30 AM
To: Erik.Bjornson@baxalta.com
Cc: tung.koh@baxalta.com; Thompson, Edward
Subject: Information Request: Study 261201 (Response Due by WEDNESDAY, September 23, 2015) - Original BLA 125566/0, Antihemophilic Factor (Recombinant), PEGylated [ADYNOVATE]

Importance: High

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 additional information to continue our review:

1. Please clarify the ratio of mean ABRs in prophylaxis/on-demand subgroups for Asian subjects in trial 261201 (safety analysis set, Table 20 in the full Clinical Study Report, although the table is labeled as Full Analysis Set).

The respective mean ABRs are given in the table as 6.9 for prophylaxis and 41.9 for on-demand. These yield a ratio value of 0.165; however, the listed value is given as 0.22. Please verify the accuracy of this value and the associated 95% CI.

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 September 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.
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