

From: Do, Yu
Sent: Friday, September 18, 2015 9:12 AM
To: Erik.Bjornson@baxalta.com
Cc: Thompson, Edward
Subject: Information Request: Response Due by MONDAY, September 21, 2015 -
Original BLA 125566/0, Antihemophilic Factor (Recombinant), PEGylated
[ADYNOVATE]

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 explain why many of the figures for Annualized Bleeding Rates (ABRs) and associated interquartile ranges, standard deviations for subjects in study 261201, and Full Analysis set listed in Table 4 in section 14 of the draft PI submitted on 11 September 2015 do not match the data in Table 25 on p. 453 of 809 of the final study report.
2. Please remove the interquartile ranges from the columns of median ABR in Table 5 in the draft PI. Without providing both extremes of the IQR, the table is confusing and there appears to be insufficient space to list the entire IQR without unacceptable crowding.
3. Please indicate whether the product has been approved in any country and, if so, if it has been marketed in any country and the dates of product launch.
4. Please be advised that the information request sent on 17 September 2015 was in regard to IND amendments for IND 15299 for this product, rather than in regard to BLA amendments.

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 21, 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
(240) 402-8343
yu.do@fda.hhs.gov

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