

From: Do, Yu
Sent: Tuesday, October 06, 2015 8:27 AM
To: Erik.Bjornson@baxalta.com
Cc: tung.koh@baxalta.com; Thompson, Edward
Subject: Information Request: Response Due by FRIDAY, October 09, 2015 - Original BLA, BL 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 submit as an amendment to this BLA a letter committing to the PREA PMRs and PMCs listed below.

PREA PMRs:

- a. Trial 261202 – PTP trial - ages zero to < 12 years
- b. Trial 261204 – Surgery trial – PEDIATRIC COMPONENT ONLY (ages 2 to < 16 years)
- c. Trial 261303 – PK guided prophylaxis PTP – PEDIATRIC COMPONENT ONLY (ages [fill in] to < 16 years)

PMCs:

- d. Trial 261204 – Surgery trial – ADULT COMPONENT ONLY
- e. Trial 261302 – Continuation trial – adults and adolescents [Note: This trial is PMC only.]
- f. Trial 261303 – PK guided prophylaxis PTP – ADULT COMPONENT ONLY
- g. Trial 261203 – PUP

2. Please include revised milestones for final protocol submission for trials 261303 and 261203, taking into account recent FDA information requests to revise these two protocols. Revise the milestones for study completion and for final report submission for these two studies as needed.

3. Please note that the pediatric components of trials 261204 and 261303 are to be PMRs only, not both PMRs and PMCs. Thus, when listing the PMCs for these 2 trials, please add "ADULT COMPONENT ONLY."

4. For all PREA PMR trials, in addition to listing the verbatim protocol title and protocol number, please specify both the lower and upper age ranges of pediatric subjects to be enrolled into each trial.

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 October 09, 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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