

From: Do, Yu
Sent: Tuesday, October 13, 2015 12:40 PM
To: Erik.Bjornson@baxalta.com
Cc: tung.koh@baxalta.com; Thompson, Edward
Subject: Information Request: Response Due by THURSDAY, October 15, 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:

In response to your proposed list of PMR and PMC studies submitted on October 06, 2015:

1. Please change the upper age limit for pediatric (adolescent) subjects from < 16 years to <17 years, as per the July 2013 FDA's Guidance Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans.
2. When submitting enrollment updates and the final study reports for applicable PMR and PMC studies for this product, please include analyses for adolescent subjects comprising ages 12 to < 17 years. This will not affect the current draft package insert, but may affect future updates to the PI resulting from inclusion of data from to-be-completed PMR and PMC studies.

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 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
FDA/OMPT/CBER/OBRR/IOD/RPMS
(240) 402-8343
yu.do@fda.hhs.gov

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you

are hereby
notified that any review, disclosure, dissemination, copying, or other action based
on the content
of this communication is not authorized. If you have received this document in
error, please
immediately notify the sender by e-mail or phone."