

From: Do, Yu
Sent: Friday, September 25, 2015 1:51 PM
To: Erik.Bjornson@baxalta.com
Cc: tung.koh@baxalta.com; Thompson, Edward
Subject: Information Request: Response Due by MONDAY, September 28, 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. Two subjects originally in trial 261201 were reported in the March 31, 2015 safety update to have had acute pancreatitis SAEs:

- a. 261201-104003
- b. 261201-109001

Please provide the concomitant medications recorded for the first patient above, taken from the time of the prior study site visit until the time of diagnosis of acute pancreatitis, as well as the baseline medical history, including HIV status, for this subject.

2. Please list the common ADYNOVATE product lot numbers, if any, that were taken by both of these subjects prior to their diagnoses of acute pancreatitis.

3. Please provide all the lot numbers and dates of administration of ADYNOVATE by lot number for each of the above subjects.

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 28, 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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