

From: Do, Yu
Sent: Wednesday, May 13, 2015 2:27 PM
To: 'Erik.Bjornson@baxalta.com'
Cc: Thompson, Edward
Subject: Information Request: Original BLA 125566/0, BAX855, Factor VIII (Recombinant), PEGylated

Dear Mr. Bjornson:

We are reviewing your original November 25, 2014 submission to BLA 125566/0 for Antihemophilic Factor (Recombinant), PEGylated. We determined that the following information is necessary to continue our review:

1. In the specification document (Section 3.2.P.5.1), the endotoxin specification is ? (b) (4) . However, it is listed as ? (b) (4) in your Validation Report (2012-(b) (4) BAX855-RFPQ1/Ver. 2). Please clarify the discrepancy and confirm if the product release specification proposed is ? (b) (4) .

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 Wednesday, May 27, 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 you have any questions, please contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov.

Sincerely,

Yu Do, M.S.
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FDA/OMPT/CBER/OBRR/IOD/RPMS
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