

From: Ward-Peralta, Cherie
Sent: Monday, October 19, 2015 10:26 AM
To: 'Fernandez, Alexander Maximilian'
Subject: STN 125577 - Information Request - Please respond by October 21, 2015

Our Reference: BL 125577/0

Baxalta US Inc.
Attention: Maximilian Fernandez, PhD
Sent by email

Dear Dr. Fernandez:

We are reviewing your December 19, 2014, biologics license application (BLA) for von Willebrand Factor (Recombinant). We determined that the following information is necessary to continue our review:

1. For all subjects who participated in the pivotal study 071001 who had missing efficacy rating scores for any bleeding episodes, please provide the subject ID and date of bleeding episode. If no subjects had missing efficacy rating scores, please state that.
2. Please provide the raw data for the efficacy rating score per each bleeding episode (date and score) so that we can confirm the mean score for each subject.

Please submit your response to this information request as an amendment to this file by October 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.

The action due date for this file is December 19, 2015.

Very Respectfully,

Cherie Ward-Peralta, M.S.

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