

From: Ward-Peralta, Cherie
Sent: Monday, October 05, 2015 2:43 PM
To: Fernandez, Alexander Maximilian (max.fernandez@baxalta.com)
Subject: STN 125577 - Information Request - Please respond by October 13, 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. In Section 3.2.S.2.6 (manufacturing process development), you state on Page 103, "In pursuance of a revised regulatory guideline, which requires the (b) (4) [REDACTED] You have made reference to this revised regulatory guideline several times in this section and the change is illustrated in Figure 17 (Page 104). Please provide the full reference to this revised regulatory guideline and indicate the section and/or page number where this change has been suggested. The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by October 13, 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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