

From: Ward-Peralta, Cherie
Sent: Tuesday, December 01, 2015 4:17 PM
To: 'Fernandez, Alexander Maximilian'
Subject: STN 125577 - Information Request - Please respond by December 4, 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:

Labeling

1. Please revise your package insert according to the tracked changes and comments made within the attached document.



pi-20151125-vo...

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 December 4, 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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Office of Blood Research and Review
Center for Biologics Evaluation and Research
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