

From: Ward-Peralta, Cherie
Sent: Wednesday, November 18, 2015 8:54 AM
To: 'Fernandez, Alexander Maximilian'
Subject: STN 125577 - Information Request - Please respond by November 25, 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. We have incorporated changes to replace ADVATE with recombinant Factor VIII except for the description of the clinical trial.



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 November 25, 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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