

From: Ward-Peralta, Cherie
Sent: Thursday, July 23, 2015 2:34 PM
To: Fernandez, Alexander Maximilian (max_fernandez@baxter.com)
Subject: STN 125577 - Information Request - Please respond by July 30, 2015

Our Reference: BL 125577/0

Baxter Healthcare Corporation
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. You have described total of (b) (4) rVWF conformance lots that were characterized using all the analytical tests. However, there is no comprehensive list of all the final drug product conformance lots that were manufactured using the current process. Please compile this list and include details about the origin of each of these lots and the physicochemical characterization and analytical test results, individually tabulated for each lot.
2. Please provide the (b) (4) .

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 July 30, 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,

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