

From: Ward-Peralta, Cherie
Sent: Wednesday, August 19, 2015 9:34 AM
To: Fernandez, Alexander Maximilian (max_fernandez@baxter.com)
Subject: FW: STN 125577 - Information Request - Please respond by September 2, 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 stated that the acceptance criteria for (b) (4) of the (b) (4) samples during cleaning validation were defined individually for each type of equipment at (b) (4). However, the reported acceptance criteria do not reflect the process capabilities as demonstrated by the results of the cleaning validation runs summarized in the table below. Please update your acceptance criteria to meet your process capabilities. Please justify your response. If you have any questions, please contact Jie He at (240) 402-9584.

(b) (4)

(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 September 2, 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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