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To: [Fernandez, Alexander Maximilian \(max.fernandez@baxalta.com\)](#); [Silvey, William Bryan \(Bryan.Silvey@baxalta.com\)](#)
Cc: [Ward-Peralta, Cherie](#)
Subject: RE: Information request Baxter rVWF BLA STN125577/0 (Acknowledgment Receipt)
Date: Thursday, August 27, 2015 4:22:00 PM
Importance: High

Our Reference: BL 125577/0
Baxter Healthcare Corporation
Attention: Alexander Fernandez, PhD

August 27, 2015
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. **Regarding cleaning validation at Thousand Oaks facility:**

- **You provided the acceptance criteria for your cleaning validation for equipment and small parts used for FDP manufacturing process (including items used for fill and finish processes, such as (b) (4) as listed in the table below. You also provided data collected during the cleaning validation of some of the equipment except for the small parts. However, the current (b) (4) acceptance criterion does not reflect the process capabilities demonstrated by the available results from the cleaning validation runs. Please update your acceptance criteria for (b) (4) to meet your process capabilities. Please justify your response.**
- **Please provide justifications on why (b) (4) is not part of the acceptance criteria**

Test	Acceptance Criteria
(b)	(4)

(b) (4)

2. Regarding (b) (4)

- Please clarify if (b) (4) are dedicated to rVWF or shared with other products
- Please provide the cleaning validation data for (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 8, 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.

Kind regards,

Jie He

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