

From: Ward-Peralta, Cherie
Sent: Thursday, May 14, 2015 11:09 AM
To: Fernandez, Alexander Maximilian (max.fernandez@baxalta.com)
Subject: STN 125577/0 - Information Request - Please respond by May 28, 2015

Our Reference: BL 125577/0

Baxter Healthcare Corporation
Attention: Maximilian Fernandez, PhD
May 14, 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:

BAX111

IR Regarding Baxter's Response (# 3.3) to FDA Review Requests Received on 30 March, 2015 (1.11.1 Quality Information Amendment)

<Endotoxin>

1. In your response # 3.3, you clarified the (b) (4) dilution is the primary sample dilution for your routine release testing. However, you indicated higher validated dilutions (b) (4) may be used to dilute the product samples when the primary sample dilution (b) (4) resulted in an invalid test due to enhancement by product sample matrix. We expect a method suitability test to be performed on each product concentration (650 IU/vial and 1300 IU/vial), as your product matrices are different; thus, the individual testing dilution selected for each product concentration should result in a qualified test performed each time. We will not accept an option to retest if the release test does not meet its qualifications the first time, as we perform confirmatory release testing of products and use the specific testing dilution specified for each product in your license application. A product is expected to pass its release test using the testing dilution qualified as suitable for the product matrix, if the test is not valid – one could assume the product matrix has changed; which would indicate a major change in the production process. Please perform method suitability testing for each product concentration and provide a specific testing dilution(s) that should result in a qualified release test, even if you need to assign different testing dilutions for each product concentration.

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 May 28, 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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