

From: Ward-Peralta, Cherie
Sent: Monday, March 16, 2015 6:51 PM
To: Agopyan, Nadia <nadia_agopyan@baxter.com>
(nadia_agopyan@baxter.com)
Subject: STN 125577/0 - Information Request - Please respond by March 30, 2015

Our Reference: BL 125577/0

Baxter Healthcare Corporation
Attention: Ms. Nadia Agopyan
March 16, 2015
Sent by email

Dear Ms. Agopyan:

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:

Bioburden

1. Please provide the (b) (4) qualification report for the bioburden test performed (b) (4) at the rVWF final drug product manufacturing stage; to include type of (b) (4), to show the product matrix is suitable for the intended test method.

Sterility

2. For the sterility method qualification (section 3.2.P.5.3; Validation Report – OR1200005-CVRRVA.03) the following information is requested to complete its review:
 - a. Please provide the volume of product sample tested in each (b) (4).
 - b. Please provide the (b) (4) that were used to qualify the product matrix for this method.

Endotoxin

3. In your report 'Quantitative Determination of Endotoxin (b) (4) in rVWF FDP', the product samples are (b) (4) (section 4.2.2 of the report). Please provide supporting background/R&D data to establish (b) (4) of the test sample effectively eliminates interference without loss of endotoxins, as stated in (b) (4). In addition, please provide CBER the detailed procedure for sample (b) (4) method and confirm all samples are (b) (4) before tested by this method.
4. Please provide CBER with the one test sample dilution that will be used for your release BET. In the qualification report provided, (b) (4) dilutions met specification, but the

chosen testing dilution was not specified; CBER requires this information to perform in-support product release testing.

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 March 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.

If you have any questions, please contact me at (240) 402-8447 or cherie.ward-peralta@fda.hhs.gov.

Sincerely,

Cherie Ward-Peralta, M.S.

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