

From: Thompson, Edward
Sent: Monday, March 16, 2015 6:37 AM
To: 'Erik Bjornson (Erik_Bjornson@baxter.com)'
Subject: Information Request for BL 125566/0

Contacts: Erik Bjornson - Baxter Healthcare Corporation

Dear Mr. Bjornson:

We are reviewing your November 25, 2014 biologics license application (BLA) for Antihemophilic Factor (Recombinant), PEGylated. We are providing the following comments and request for additional information to continue our review:

Sterility

1. In the Sterility Test Validation Report (Validation Report – OR-12-00006-53-VR.01) the following information is requested to complete its review:
 - a. Please provide the volume of product sample tested in each medium.
 - b. Please provide the indicator microorganisms confirmatory CFU counts that were used to inoculate the media as part of the qualification of the product matrix for this method.
 - c. Please provide results obtained from negative control.

Bioburden

2. The bioburden test method for the (b) (4) was performed with (b) (4) according to Bioburden method validation protocol (b) (4)-65-0924O). However, CBER finds bioburden method validation report (Report (b) (4)-65-0924O) incomplete. CBER requests that you provide a new bioburden method validation report showing suitability of the (b) (4) method in the presence of product performed with (b) (4) as in accordance with (b) (4)



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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.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is November 25, 2015.

Please send an acknowledgement for receipt of this request.

If you have any questions, please contact me at (240) 402-8443.

Sincerely,

Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/RPMS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our Reference: BL 125566/0

Baxter Healthcare Corporation
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March 16, 2015
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