

From: Maruna, Thomas
Sent: Thursday, October 15, 2015 10:46 AM
To: KevinDarryl.White@csllabehring.com
Subject: Information Request - BLA 125591.0 - Please Respond by October 29, 2015

Importance: High

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
October 15, 2015
Sent by email

Dear Mr. White:

We are reviewing your May 29, 2015 biologics license application (BLA) for the following:

STN	Name of Biological Products
125591/0	Antihemophilic Factor (Recombinant), Single Chain

We determined that the following information is necessary to continue our review:

Bioburden, Sterility and Endotoxin Test

1. Please provide the test qualification reports for the (b) (4) showing the CSL627 (b) (4) (b) (4) matrix is suitable for the intended test method in accordance with (b) (4) Please include data showing the (b) (4) in the presence and absence of the (b) (4) (b) (4)
2. Please provide more information for the sterility test qualification report for the CSL627 drug product matrix showing the product matrix is suitable for the intended test method in accordance with (b) (4) Specifically, please include conformance lot numbers used in the qualification and their respective potencies.
3. Please provide the (b) (4) bacterial endotoxin test qualification reports showing the CSL627 (b) (4) drug product matrices are suitable for the intended test method (in accordance with (b) (4) to include maximal valid dilution, tested dilutions, positive product control percent recoveries, lot numbers with their respective potencies, selected testing dilution and endotoxin test results.

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 responses as an amendment to this file by October 29, 2015 referencing the date of this request.

The action due date for this file is May 28, 2016.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP)^{CM}

Lieutenant, U.S. Public Health Service

Senior Regulatory Management Officer

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