

From: Maruna, Thomas
Sent: Tuesday, December 15, 2015 1:06 PM
To: 'KevinDarryl.White@csllabehring.com'; 'Angela.Azzara@csllabehring.com'
Subject: December 15. 2015 Information Request - BLA 125591.0 - Please Respond by December 29. 2015

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
December 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:

With reference to testing instruction Q-16-410, version 4.0, “(b) (4) [REDACTED] recombinant factor VIII”:

1. The testing instruction mentions an “accuracy control sample” prepared by (b) (4) [REDACTED]” Please provide the following information, missing from the testing instruction:
 - a. How results from analysis of the “accuracy control sample” are used and what are the acceptance criteria for the “accuracy control sample”;
 - b. If the “accuracy control sample” is being prepared from each lot analyzed or if a single “accuracy control sample” sample is used for the analysis of multiple lots.
2. Lot (b) (4) [REDACTED] is reported with (b) (4) [REDACTED] in the batch analysis. Please provide the results and acceptance criteria for analysis of the “accuracy control sample” for this lot.

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 December 29, 2015 referencing the date of this request.

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

If you have any questions, please contact me.

Very Respectfully,

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

Lieutenant, U.S. Public Health Service

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