

**From:** Maruna, Thomas  
**Sent:** Tuesday, December 15, 2015 1:06 PM  
**To:** 'KevinDarryl.White@cslbehring.com'; 'Angela.Azzara@cslbehring.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:

<b>STN</b>	<b>Name of Biological Products</b>
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)<sup>CM</sup>

Lieutenant, U.S. Public Health Service

Senior Regulatory Management Officer

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Blood Research and Review

10903 New Hampshire Ave.

Silver Spring, MD 20993

[thomas.maruna@fda.hhs.gov](mailto:thomas.maruna@fda.hhs.gov)

O: (240) 402-8454

[www.usphs.gov](http://www.usphs.gov)



"THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.