

From: Maruna, Thomas
Sent: Wednesday, January 20, 2016 2:44 PM
To: KevinDarryl.White@cslbehring.com; 'Angela.Azzara@cslbehring.com'
Subject: Second Sample IR for 125591/0 - Please Respond by February 3. 2016

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
July 20, 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 is necessary to continue our review:

1. Please provide an additional 2 vials per lot for each of the following lots:

Drug Product Batch Number	
250 IU: Lot (b) (4)	
250 IU: Lot (b) (4)	
500 IU: Lot (b) (4)	
1000 IU: Lot (b) (4)	
1000 IU: Lot (b) (4)	
3000 IU: Lot (b) (4)	

2. For the (b) (4) assay, please provide 6 vials of “accuracy control sample”, along with a COA for this “accuracy control sample” if it is a different lot from what was sent to CBER in December, 2015.
3. Ship samples and reagents to the address listed below:

Alfred Del Grosso
Chemistry Team Lead
Food and Drug Administration
Center for Biological Evaluation and Research

Division of Biological Standards and Quality Control
10903 New Hampshire Avenue
WO75, G-717
Silver Spring, MD 20993-0002

Please send samples by February 3, 2016 and notify CBER prior to shipment of an expected date for receipt.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

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

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

O: (240) 402-8454

www.usphs.gov



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