

From: Maruna, Thomas
Sent: Thursday, March 10, 2016 10:28 AM
To: 'Angela.Azzara@csllabehring.com'; KevinDarryl.White@csllabehring.com
Subject: March 10. 2016 Information Request - BLA 125591.0 - Please Respond By March 18. 2016

Importance: High

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
March 10, 2016
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 have determined that the following information is necessary to continue review:

1. In the document "Summary report on the structural characterization of recombinant single-chain Factor VIII (rVIII-SingleChain)" in section 3.2.S.3.1-1, you included detailed structural characterization of the (b) (4)
(b) (4) If available, please provide the (b) (4) (b) (4)

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 March 18, 2016 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), CPH
Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer
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