

**From:** Maruna, Thomas  
**Sent:** Wednesday, January 13, 2016 3:10 PM  
**To:** KevinDarryl.White@cslbehring.com; 'Angela.Azzara@cslbehring.com'  
**Subject:** January 13. 2016 Information Request - BLA 125591.0 - Please Respond by January 22. 2016

CSL Behring Recombinant Facility AG  
Attention: Mr. Kevin Darryl White  
January 13, 2016  
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:

1. In the Section 3.2.S.2.3.8, CSL Behring stated that (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 January 22, 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)<sup>CM</sup>  
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Senior Regulatory Management Officer  
Food and Drug Administration  
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