

**From:** Maruna, Thomas  
**Sent:** Thursday, November 05, 2015 2:46 PM  
**To:** 'KevinDarryl.White@cslbehring.com'  
**Cc:** 'Angela.Azzara@cslbehring.com'  
**Subject:** 05Nov2015 Information Request - STN 125591.0 - Please Respond by November 19. 2015

**Importance:** High

CSL Behring Recombinant Facility AG  
Attention: Mr. Kevin Darryl White  
November 5, 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:

1. In table format, in reference to the CSL Behring facility, please identify all areas (i.e. Production rooms, Support areas, etc.), utilities (i.e. HVAC, water, etc.), and equipment (i.e. autoclaves, washers, other production equipment, etc.) that are shared with rIX-FP manufacturing.
  - a. If applicable, please identify the Facility and Equipment related documents in the rVIII-SingleChain BLA that were already submitted as part of the rIX-FP application. In other words, are there any identical documents in this application as those in the prior submission?

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 November 19, 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

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