

**From:** Maruna, Thomas  
**Sent:** Thursday, November 05, 2015 3:39 PM  
**To:** 'KevinDarryl.White@cslbehring.com'  
**Cc:** 'Angela.Azzara@cslbehring.com'  
**Subject:** 05Nov2015-2 Information Request - STN 125591.0 - Please Respond by November 11. 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:

We have found some apparent discrepancies and missing information. One exclusion criterion for trial 1001 was “Human immunodeficiency virus (HIV) positive subjects with a CD4 count < 200/mm<sup>3</sup>, in their medical history or at Screening if available results are older than 1 year.” Can you please explain the following data?

1. In our review of the submitted data, we found HIV data for 165 subjects in the Medical History section; however, 210 study subjects are listed in the Demographics section.
2. There were 27 subjects in Part 1 and 26 of these subjects continued to Part 2. We were only able to identify HIV records for three subjects ((b) (6) [REDACTED])
3. In Part 3, 14 subjects had a comment “NOT DONE” in column MHSTAT and no results found in the submission.
4. In the submitted materials, it was indicated that 18 subjects were HIV positive; however we could only find CD4 counts for 15 of these subjects.

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 11, 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.