

From: Maruna, Thomas
Sent: Tuesday, November 24, 2015 11:19 AM
To: 'KevinDarryl.White@cslbehring.com'
Cc: 'Angela.Azzara@cslbehring.com'
Subject: November 24. 2015 Information Request - STN 125591.0 - Please Respond by December 8. 2015

Importance: High

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
November 24, 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 information is necessary to continue our review:

1. Please clarify the following apparent discrepancies:
 - a. Trial 1001, Table 11-24: 173 bleeding episodes are reported, but 616 is also given. The total of bleeding sites totals greater than 100% (91.9% joint, 10.7% muscle, 11.2% other). In addition, $566+66+69 = 701$, not 616.
 - b. Trial 1001, Table 11-25: This table lists a total of 872 bleeding episodes (not 173).

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 December 8, 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)^{CM}
Lieutenant, U.S. Public Health Service

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