

From: Maruna, Thomas
Sent: Wednesday, January 20, 2016 10:36 AM
To: 'Angela.Azzara@csllbehring.com'; KevinDarryl.White@csllbehring.com
Cc: Khrenov, Alexey (CBER)
Subject: January 20. 2016 Information Request - BLA 125591.0 - Please Respond by February 3. 2016

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
January 20, 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 determined that the following information is necessary to continue our review:

During in-support testing of lots (b) (4) (both 250 IU strength) (b) (4) according to testing instruction Q-16-410 (version 5.0), both samples, when tested after reconstitution to a concentration of (b) (4) (see sample image below), which was not observed in samples of higher dosage strengths. (b) (4) failing the acceptance criteria for (b) (4) Release limit and (b) (4) Shelf-life limit).

(b) (4)

Please provide the following information to address this issue:

1. Please indicate if this (b) (4) has previously been observed in the testing of rFVIII-SC (b) (4) drug product (DP).

2. (b) (4), please provide the information regarding the characterization and identity of the (b) (4), and the results of other relevant studies.
3. Please review the results of previous testing of DP lots (b) (4) in question.
4. Please provide the results of the latest time-points in the ongoing stability studies on the testing of DP lots (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 February 3, 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)

Lieutenant, U.S. Public Health Service

Senior Regulatory Management Officer

Food and Drug Administration

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