

From: Maruna, Thomas
Sent: Friday, December 04, 2015 1:26 PM
To: 'Angela.Azzara@cslbehring.com'; 'KevinDarryl.White@cslbehring.com'
Subject: December 4. 2015 Information Request (Clinical) - BLA 125591.0 - Please Respond by December 18. 2015

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
December 4, 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 identify the specific reasons for discontinuation from the study for the following subjects in study CSL627_1001:

Withdrawal by subject

2760030/1001
2760030/1005
2760030/1006
2760034/1002
3800023/1004
8260008/1003
8400154/1006
8400155/1001

Physician Decision

8400184/1003

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 18, 2015 referencing the date of this request. If you are unable to respond by the requested date, please propose an alternative.

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

Senior Regulatory Management Officer

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Blood Research and Review

10903 New Hampshire Ave.

Silver Spring, MD 20993

thomas.maruna@fda.hhs.gov

O: (240) 402-8454

www.usphs.gov



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