

From: Maruna, Thomas
Sent: Monday, February 22, 2016 1:05 PM
To: 'Angela.Azzara@cslbehrling.com'; KevinDarryl.White@cslbehrling.com
Cc: Campbell, Karen M
Subject: February 22. 2016 Information Request - BLA 125591.0 - Please Respond By February 29. 2016

Importance: High

CSL Behrling Recombinant Facility AG
Attention: Mr. Kevin Darryl White
February 22, 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:

1. You provided the potency of your control sample (b) (4) which is based on the Chromogenic Assay. Please provide the potency value for this control (b) (4) based on the one-stage clotting assay as well.

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 29, 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), CPH
Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer
Food and Drug Administration
Center for Biologics Evaluation and Research
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