

From: Maruna, Thomas
Sent: Monday, April 11, 2016 10:27 AM
To: KevinDarryl.White@cslbehring.com; 'Angela.Azzara@cslbehring.com'
Subject: April 11. 2016 PMC Concurrence Request - BLA 125591.0 - Please Respond By April 18. 2016

Importance: High

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
April 11, 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 have included the following proposed Post-Marketing Commitments (PMCs) for your concurrence:

1. CSL Behring commits to investigate the (b) (4) [REDACTED]
[REDACTED]. We commit to submit a Supplement containing the Postmarketing Commitment - Final Study Report by May 31, 2017.
2. CSL Behring commits to develop and validate an (b) (4) [REDACTED] method in which the (b) (4) [REDACTED]. We commit to submit a Supplement containing the Postmarketing Commitment - Final Study Report by May 31, 2017.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

If CSLB concurs, please submit your written agreement to these PMCs, as stated, as an amendment to this file by April 18, 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

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