

From: Maruna, Thomas
Sent: Friday, May 13, 2016 11:49 AM
To: KevinDarryl.White@cslbehring.com; 'Angela.Azzara@cslbehring.com'
Cc: Frost, Mitchell M
Subject: FDA Request for Info and Labeling - BL 125591/0 -
Antihemophilic Factor
(Recombinant), Single Chain (Please respond by May 17, 2016)
Attachments: annotated-draft-labeling-text.05.12.2016.docx

Importance: High

Our Reference: BL 125591/0

CSL Behring Recombinant Facility AG
Attention: Kevin D. White, MBA, RAC
May 13, 2016
Sent by email

Dear Mr. White:

We are reviewing your May 29, 2015, biologics license application (BLA) for Antihemophilic Factor (Recombinant), Single Chain. We are providing the revised labeling for your review and acceptance:

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 response to this information request as an amendment to this file as soon as possible, but no later than May 17, 2016, referencing the date of this request. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

The action due date for this file is May 28, 2016.

If you have any questions during this week, please contact me.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH
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Senior Regulatory Management Officer
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