

From: Maruna, Thomas
Sent: Thursday, May 19, 2016 2:14 PM
To: KevinDarryl.White@cslbehring.com; 'Angela.Azzara@cslbehring.com'
Cc: Frost, Mitchell M; Khrenov, Alexey (CBER)
Subject: FDA Request for Info - Labeling - BL 125591/0 -
Antihemophilic Factor
(Recombinant), Single Chain (Please respond by May 20, 2016)
Attachments: annotated-draft-labeling-text.05.18.2016.docx

Importance: High

Our Reference: BL 125591/0

CSL Behring Recombinant Facility AG
Attention: Kevin D. White, MBA, RAC
May 19, 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.

Additionally, please update your US Pharmacovigilance (PV) Plan by putting the potential risk "clinical impact of non-inhibitory antibodies" back in.

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 20, 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
Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer
Food and Drug Administration

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