

From: Kelly, Sunday
Sent: Monday, April 25, 2016 9:28 AM
To: KevinDarryl.White@cslbehring.com
Cc: Maruna, Thomas
Subject: FDA Request for Info and Labeling - BL 125591/0 -
Antihemophilic Factor
(Recombinant), Single Chain (Please respond by May 2, 2016)
Attachments: annotated-draft-labeling-text April 25, 2016.docx

Importance: High

Sent on behalf of LT Thomas Maruna

Our Reference: BL 125591/0

CSL Behring Recombinant Facility AG
Attention: Kevin D. White, MBA, RAC
April 25, 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 labeling and requests to continue our review:

1. Revise the presentation of the potencies on the labels (vial and carton) to reflect the nominal potencies. For example, "1000 IU Range."
2. Add the actual potency on each vial container label.
3. Add latex information on the carton labels.

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 2, 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.

Sincerely,
Sunday L. Kelly, MS, RAC, PMP
Regulatory Project Manager
U.S. Food & Drug Administration
Center for Biologics Evaluation and Research
Office of Blood Research and Review
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