

From: Maruna, Thomas  
Sent: Tuesday, May 17, 2016 11:04 AM  
To: KevinDarryl.White@cslbehrling.com; 'Angela.Azzara@cslbehrling.com'  
Cc: Frost, Mitchell M; Khrenov, Alexey (CBER)  
Subject: FDA Request for Info - Labeling - DHCP Letter - BL 125591/0 -  
Antihemophilic  
Factor (Recombinant), Single Chain (Please respond by May 19, 2016)  
Attachments: annotated-draft-labeling-text.05.16.2016ak.docx; draft-  
dhcp-letter-  
redline.doc

Importance: High

Our Reference: BL 125591/0

CSL Behrling Recombinant Facility AG  
Attention: Kevin D. White, MBA, RAC  
May 17, 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 and Dear Health  
Care Provider Letter 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 19, 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  
Center for Biologics Evaluation and Research  
Office of Blood Research and Review

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