

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

Center for Biologics Evaluation and Research  
Office of Blood Research and Review  
10903 New Hampshire Ave.  
Silver Spring, MD 20993  
thomas.maruna@fda.hhs.gov  
O: (240) 402-8454  
www.usphs.gov

"THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.