

From: Maruna, Thomas  
Sent: Monday, February 22, 2016 12:47 PM  
To: 'Angela.Azzara@cslobehring.com'; KevinDarryl.White@cslobehring.com  
Subject: Revised Draft Label - BLA 125591.0 - Please Respond by  
February 29, 2016  
Attachments: labeling-draft text.doc

CSL Behring Recombinant Facility AG  
Attention: Mr. Kevin Darryl White  
February 22, 2016  
Sent by email

Dear Mr. White:

We are reviewing your May 29, 2015 biologics license application (BLA) for the following:

STN	Name of Biological Products
125591/0	Antihemophilic Factor
(Recombinant), Single Chain	

To expedite our review of the Afstyla label, please review all appropriate sections of the submitted draft label to reflect the final pediatric data as submitted in the final study report for CSL627-3002, the pediatric trial, and submit a revised draft label via amendment to the BLA.

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 responses as an amendment to this file by February 29, 2016 referencing the date of this request. The action due date for this file is May 28, 2016. If you have any questions, please contact me.  
Very Respectfully,

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