

From: Maruna, Thomas
Sent: Thursday, May 19, 2016 1:50 PM
To: KevinDarryl.White@cs Behring.com; 'Angela.Azzara@cs Behring.com'
Cc: Hu, Jiang (Jessica) (CBER)
Subject: May 19. 2016 Information Request - BLA 125591.0 - Please Respond By March 9. 2016

Importance: High

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
May 19, 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

We have determined the following information is necessary to continue our review:

1. Please submit the ADAM dataset and SAS code to verify the pediatric results in Table 7 (Efficacy of AFSTYLA in Control of Bleeding) of labeling draft (1.4.1.3, page 14 of 25);
2. Please submit the SAS code (b) (4)

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 ASAP, but no-later-than May 20, 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
Food and Drug Administration
Center for Biologics Evaluation and Research

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