

From: Maruna, Thomas
Sent: Monday, March 07, 2016 12:59 PM
To: 'Angela.Azzara@cslbehrling.com'; KevinDarryl.White@cslbehrling.com
Cc: Baum, Victor
Subject: March 7. 2016 Information Request - BLA 125591.0 - Please Respond By March 9. 2016

Importance: High

CSL Behrling Recombinant Facility AG
Attention: Mr. Kevin Darryl White
March 7, 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 reviewed amendment 25 to BLA 125591, which represents labeling changes to reflect the final pediatric data in CSL627_3002. Table 6 of that label reports on the pharmacokinetic parameters of 39 children who received Afstylal 50 IU/kg. In our review it appears that there were 38 appropriate subjects for this analysis. See, e.g. Tables 11-8 and 11-9 on pages 82 and 83 of the final Clinical Study Report for CSL627_3002.

Subject (b) (6) received an actual dose of 56.4 IU per kg, beyond the allowable tolerance limit of $\pm 10\%$.

Please explain why this subject's data should not be excluded from Table 6 of the label.

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 March 9, 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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