

From: Maruna, Thomas
Sent: Saturday, August 15, 2015 11:12 AM
To: KevinDarryl.White@cslbehring.com
Subject: August 15, 2015 Information Request - BLA 125591.0 - Please Respond by August 21, 2015

Importance: High

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
August 15, 2015
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 determined that the following information is necessary to continue our review:

1. Please explain the following apparent discrepancy. In the Interim Pharmacokinetic and Safety Report for trial CSL627_3002 (the pediatric trial) in Section 11.5.3 (p. 64) it indicates that “At the last sampling time (48 h) 3 of 6 subjects...had FVIII activity levels >1%”. However, section 13 (p. 81) states that “All subjects had FVIII activity levels >1% at the last sampling point (48h)...”

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 August 21, 2015 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)^{CM}
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