

From: Maruna, Thomas
Sent: Monday, July 20, 2015 10:32 AM
To: KevinDarryl.White@cs Behring.com
Subject: July 20, 2015 Information Request - Please Respond by July 27, 2015

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
July 20, 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:

Clinical

1. In BLA 125591/0 preliminary data for the pediatric trial 3002 are included. In these data the two pediatric cohorts are < 6 years old and 6 to <12 years old. How many of these children were 0-2 years old?

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 July 27, 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,

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