

From: Maruna, Thomas
Sent: Thursday, November 05, 2015 2:46 PM
To: 'KevinDarryl.White@cslbehring.com'
Cc: 'Angela.Azzara@cslbehring.com'
Subject: 05Nov2015 Information Request - STN 125591.0 - Please Respond by November 19. 2015

Importance: High

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
November 5, 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. In table format, in reference to the CSL Behring facility, please identify all areas (i.e. Production rooms, Support areas, etc.), utilities (i.e. HVAC, water, etc.), and equipment (i.e. autoclaves, washers, other production equipment, etc.) that are shared with rIX-FP manufacturing.
 - a. If applicable, please identify the Facility and Equipment related documents in the rVIII-SingleChain BLA that were already submitted as part of the rIX-FP application. In other words, are there any identical documents in this application as those in the prior submission?

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 November 19, 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}

Lieutenant, U.S. Public Health Service

Senior Regulatory Management Officer

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Blood Research and Review

10903 New Hampshire Ave.

Silver Spring, MD 20993

thomas.maruna@fda.hhs.gov

O: (240) 402-8454

www.usphs.gov



"THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.