

From: Maruna, Thomas
Sent: Thursday, June 18, 2015 11:19 AM
To: KevinDarryl.White@cslbehring.com
Subject: June 18, 2015 Information Request - STN 125591.0 - Please Respond by July 2, 2015

Importance: High

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
June 18, 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 reference to the (b) (4) Facility:
 - a. Please provide the regulatory inspectional history for the last two years.
 - b. What other US approved, non-US approved, or investigational products are produced in the same rooms / areas used to produce rVIII-Single Chain Bulk Drug Intermediate (BDI)?
 - c. Please provide a table identifying the product contact equipment that is shared with other US approved, non-US approved, or investigational products. Please confirm that cleaning procedures are validated for all product contact equipment.
 - d. Please identify any new construction (i.e. building remodeling) or modification to utilities (i.e. HVAC, Water, and Pharmaceutical Gases) that has occurred to accommodate rVIII-Single Chain manufacturing, and provide the qualification status.
2. Please provide, in table format, the specific tests and the product stage tested, related to rVIII-Single Chain, performed (to be performed for commercial product) at the following testing facilities:
 - a. (b) (4)

b. (b) (4)

d. CSL Behring GmbH, Emil-von-Behring Straße 76 35041 Marburg, Germany

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 2, 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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