

From: Maruna, Thomas
Sent: Wednesday, January 13, 2016 3:39 PM
To: KevinDarryl.White@cslbehring.com; 'Angela.Azzara@cslbehring.com'
Subject: January 13. 2016 (2) Information Request - BLA 125591.0 - Please Respond by January 22. 2016

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin Darryl White
January 13, 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

Please update Section 1.12.14 of your submission, stating that, to your knowledge, no extraordinary circumstances exist.

Please reference 21 CFR 25.15(d): A person submitting an application or petition of a type subject to categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.34, or proposing to dispose of an article as provided in 25.30(d) or 25.32(h), is not required to submit an EA if the person states that the action requested qualifies for a categorical exclusion, citing the particular categorical exclusion that is claimed, and states that to the applicant's knowledge, no extraordinary circumstances exist.

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 January 22, 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)^{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.