



Our STN: BL 125582/0

**BLA FILING REVIEW
ISSUES IDENTIFIED**

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin D. White
CSL Behring
1020 First Avenue
P.O. Box 61501
King of Prussia, PA 19406-0901

Dear Mr. White:

Please refer to your biologics license application (BLA), submitted under section 351 of the Public Health Service Act, and to our filing letter dated February 3, 2015. While conducting our filing review, we identified the following potential review issue:

1. From the Common Technical Document, Module 3, you have omitted:

Non-proprietary information on Facility / Equipment related to rIX-FP operations for the (b) (4), recommended per *Guidance for Industry: For The Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use-Aug 1996*, (please reference the information requirements described in *Section II: Drug Substance; B. Manufacturer(s): 2.Floor Diagrams, 3.Other Products, & 4.Contamination Precautions; and C. Method(s) of Manufacture: 2.Flow Charts*).

As the BLA needs to be a stand-alone document, this information needs to be submitted as part of the BLA. Other supporting information may be provided in the referenced DMF, (b) (4)

We are providing the above comments to give you preliminary notice of potential review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our complete review. Issues may be added, deleted, expanded upon, or modified as we review the application. If you respond to these issues during this review cycle, we may not consider your response before we take an action on your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Manager, Edward Thompson, at (240) 402-8443.

Sincerely,

Basil Golding, MD
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research