



Our STN: BL 125582/0

**BLA FILING NOTIFICATION**

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:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated December 5, 2014 for Coagulation Factor IX (Recombinant), Albumin Fusion Protein to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review classification for this application is Standard. Therefore, the review goal date is December 5, 2015. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which include the timeframes for FDA internal milestone meetings. We plan to hold our internal mid-cycle review meeting on May 12, 2015. Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process.

We will contact you regarding your proposed labeling no later than November 5, 2015. If post marketing study commitments (506B) are required, we will contact you no later than November 5, 2015.

At this time, we have no plans to present this application to an Advisory Committee.

While conducting our filing review, we identified potential review issues and will be communicating them to you on or before February 17, 2015.

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

Sincerely,

Iliana Valencia, MS  
Chief  
Regulatory Project Management Staff  
Office of Blood Research and Review  
Center for Biologics  
Evaluation and Research