



Our STN: BL 125582/0

MAJOR AMENDMENT ACKNOWLEDGEMENT

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

Dear Mr. White:

We received your August 31, 2015 amendment to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) for Coagulation Factor IX (Recombinant), Albumin Fusion Protein.

We consider your submission a major amendment under the reauthorization of the prescription drug user fee program in the *Food and Drug Administration Safety and Innovation Act* of 2012 and will add an additional three months to the time by which we should complete our review. Therefore, the action due date is March 5, 2016.

We will contact you regarding your proposed labeling no later than February 4, 2016. If post marketing study commitments (506B) are required, we will contact you no later than February 4, 2016.

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