



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our Reference: BL 125582/0

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin D White
January 29, 2016
Sent by email

Dear Mr. White:

We are reviewing your December 5, 2014 biologics license application (BLA) for Coagulation Factor IX (Recombinant), Albumin Fusion Protein. We request that you make the following postmarketing commitments:

1. Please confirm your agreement to the post-marketing commitments and report submission dates as presented below:

- a. CSL Behring (CSLB) will develop a (b) (4) assay for (b) (4)

The results of the method validation study and justification for the release specification of this (b) (4) test will be submitted to the FDA as a Prior Approval Supplement by 15 August 2016 labeled as a Supplement Contains Postmarketing Commitment – Final Study Report.

Final Report Submission: 15 August 2016

- b. CSLB will continue to investigate (b) (4)

CSLB will perform this study following the 3-stage plan outlined in Amendment 125582/0.48 dated 18 December 2015. CSLB will submit to the FDA a Postmarketing Commitment - Status Update at the end of the first 2 stages of the study by 31 March 2016 and 31 August 2016, respectively. CSLB will submit the final study report to the FDA under Postmarketing Commitment – Final Study Report by 31 March 2017.

Final Report Submission: 31 March 2017

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 response to this information request as an amendment to this file by February 5, 2016 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is March 5, 2016.

Please send an acknowledgement for receipt of this request.

If you have any questions, please contact me at (240) 402-8443.

Sincerely,
Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/RPMS