



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
August 26, 2015
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 are providing the following comments and request for additional information to continue our review:

With reference to your 26 June 2015 responses to the Inspectional Observations listed on Form FDA 483, please submit the following documents:

1. 26 June 2015 responses to the Inspectional Observations
2. Revised sections of the SOP 505042 "Validation of analytical methods" along with the confirmation that revised SOP has been made effective.
3. Revised sections of the SOP 555032 "Compilation, Approval and Release of Stability Study Plans, Tables and Reports" along with the confirmation that revised SOP has been made effective.

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 September 7, 2015 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 December 5, 2015.

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

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Thank you.