



Our Reference: BL 125582/0

CSL Behring Recombinant Facility AG  
Attention: Mr. Kevin D White  
September 4, 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:

The response from CSL Behring received on 08-07-15 to question to the following question is inadequate. The only (b) (4) data that was provided in the sponsor response was from DS lot # (b) (4). Data for at least 3 of the refined pilot scale (b) (4) lots and the two other validated commercial scale lots (b) (4) should also be submitted using the same criteria that was followed for CSL Behring's response to question 1 of the response submitted on 08-07-15 .

Reviewer Question#1 from the information request transmitted on 07-23-15

(b) (4)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

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 11, 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