



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

In reference to the “Sterile Water for Injection” (WFI diluent) manufactured in (b) (4)

1. Please confirm the fill volume and container closure (size, materials of construction) used for the WFI diluent for rIX-FP.
2. Is any WFI diluent, manufactured in (b) (4) co-packaged with other U.S. approved products? Please provide a list of those products (with STN#) including the diluent fill volumes and container/closure.
3. Do you commercially distribute any WFI diluent manufactured in (b) (4) as a stand-alone U.S. marketed product (approved under a NDA or ANDA)?

4. In reference to the (b) (4) , for the each of the equipment listed:

(b) (4)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

In table format, please provide the following information:

- a. Has cleaning validation (for evaluation of the removal of CSL654 residue) been performed for the equipment? If so, provide the protocol number. If not, provide a justification.
- b. When was the last cleaning validation or revalidation study performed?
- c. What are the acceptance criteria (i.e. assays for residue and their limits) for each cleaning validation?

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 January 28, 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

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Thank you