



Our Reference: BL 125582/0

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin D White
February 8, 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. In reference to the Container Closure associated with the Sterile Water for Injection to be copackaged with IDELVION, specifically the 6mL injection vial with stopper and cap:

The Agency expects that container-closure integrity be demonstrated / validated through an established physical test (i.e. (b) (4)) on product units that have been exposed to (b) (4)

- a. Have you validated the physical container closure integrity? If so, please provide a summary of the study including acceptance criteria and results. If not, please provide your justification.
 - b. Do you test for physical Container Closure Integrity, at a minimum, at product release? If not, please provide your justification.
2. In reference to the cleaning of any (shared or non shared) product contact equipment used in the filling of Sterile Water for Injection (to be copackaged with IDELVION), please provide the following:
 - acceptance criteria (with justification of limits) for the associated cleaning validation,
 - reference to specific cleaning validation protocol and established Cleaning procedure(s), and
 - and the date of the last cleaning validation or revalidation.

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 12, 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