

From: Thompson, Edward
Sent: Monday, February 09, 2015 3:26 PM
To: 'Kevin Darryl (KD) White (Kevin.White@cslbehring.com)'
Cc: Monica.Richardson@cslbehring.com
Subject: Information Request for BL 125582/0

Contacts: Kevin Darryl (KD) White - CSL Behring

Dear Mr. White:

We are reviewing your December 5, 2014 biologics license application (BLA) for Coagulation Factor IX (Recombinant), Albumin Fusion Protein. We determined that the following information is necessary to continue our review:

1. As follow-up from your Amendment in response to our Information Request on 12/22/14, please confirm that no U.S. approved intermediate or bulk Drug Substance processing occurs at the CSLB Marburg Site.
2. Please identify the Purification Suite used for the processing of CL654 (rIX-RP) at the (b) (4) (note: this information is not included in the latest amendment/revision of the DMF)? Has this suite been inspected by the FDA?



125582_0_Origina...

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 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

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone and return it to us at the above address by mail. Thank you.



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
February 9, 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 determined that the following information is necessary to continue our review:

1. As follow-up from your Amendment in response to our Information Request on 12/22/14, please confirm that no U.S. approved intermediate or bulk Drug Substance processing occurs at the CSLB Marburg Site.
2. Please identify the Purification Suite used for the processing of CL654 (rIX-RP) at the (b) (4) (note: this information is not included in the latest amendment/revision of the DMF)? Has this suite been inspected by the FDA?

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 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

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW
If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail.
Thank you