

From: Thompson, Edward
Sent: Friday, April 24, 2015 7:21 AM
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. In table format, please provide a list of all the water systems (i.e. Purified, WFI, and include Pure Steam) in Buildings (b) (4) including system ID numbers, dates of installation, dates of qualification, qualification protocol numbers). Please include a summary of the uses of the product water (or steam) from each system in the table.
2. To expedite review, you may submit the electronic document directly to Donald Ertel via email (Donald.Ertel@fda.hhs.gov) prior to uploading into eCTD. Feel free to contact Mr. Ertel via phone (240-402-9511) or email with any questions or concerns.



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 May 1, 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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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
April 24, 2015
Sent by email

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Thank you