

From: Thompson, Edward
Sent: Wednesday, April 15, 2015 3:15 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. Section 12.7.2.3 states:

No treatment-emergent abnormal results were observed with the exception of specific gravity and pH; none of these findings were considered to be clinically significant (Tables 14.4.6.2, and 14.4.6.4).

Please refer to the clinical lab data for the trial CSL654-3001 from subjects:

(b) (6)

These subjects' clinical lab data are notable for normal screening urinalysis, followed by more than 1 sample with a positive urine protein, and without detection of blood in the same sample.

Please provide an analysis of these subjects' urine chemistry findings.



125582.0 Origin...

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 April 23, 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 15, 2015
Sent by email

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