

From: Thompson, Edward
Sent: Tuesday, May 26, 2015 9:12 AM
To: 'Kevin Darryl (KD) White (Kevin.White@cslbehrlng.com)'
Cc: Monica.Richardson@cslbehrlng.com
Subject: Information Request for BL 125582/0

Contacts: Kevin Darryl (KD) White - CSL Behrlng

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:

An FDA nephrologist reviewed the findings from subjects in study 3001. These are additional queries regarding this study:

1. The results in the laboratory data set (Study 3001) for urine protein were positive or negative. The typical result of a urine dip stick for protein is negative or a graded result from 1+ to 4+. What were the actual test results in these subjects?

Subject (b) (6) .

2. In the applicant's laboratory dataset, the end-of-study value for urine protein is given as "1". Please clarify what "1" means. The applicant should also provide additional information on the medications that were taken (names and dates of administration). It seems likely that the proteinuria seen in this subject was caused by other factors, but the applicant should provide the requested information.

There is no apparent cause for urine protein findings in Subject (b) (6) . Please provide a possible explanation for this finding, and additional information on the subject's course.



125582_0_Orig...

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 June 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



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
May 26, 2015
Sent by email

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