



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
July 13, 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. We have reviewed your responses to our request for additional information regarding the four subjects who had a normal screening urinalysis and then developed a positive test for protein in the urine without blood on more than one sample. We have determined that additional data is needed to further evaluate the possible association between proteinuria and rIX-FP. This objective can be achieved in the currently ongoing extension study (3003). Please revise the protocol to include:
 - a. Urinalysis, spot urine protein/creatinine ratio, and fasting glucose monitoring now (or at the time of enrollment), every 6 months, and at the end of the trial for all enrolled subjects.
 - b. A minimum number of naïve subjects that will be treated.
 - c. A planned clinical work-up/further evaluation of subjects with clinically relevant abnormal urinalysis results or new onset of elevated protein-creatinine ratios.

FDA would consider this revised ongoing extension study as a postmarketing commitment study. Please provide a schedule of milestones for the study, and include target dates for submission of interim and final study reports.

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 July 27, 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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Thank you.