

From: Thompson, Edward
Sent: Thursday, December 04, 2014 12:35 PM
To: 'Steve McGregor (smcgregor@ebsi.com)'
Subject: Information Request for BL 125426/0

Contacts: Steve McGregor

Dear Mr. McGregor:

We are reviewing your biologics license application (BLA) dated April 5, 2012 for Coagulation Factor IX (Recombinant). We determined that the following information is necessary to continue our review:

1. Please submit an amendment containing the SAS transport files (.xpt) for the data tables used to generate the annexes attached to the revised Immunogenicity Risk Assessment in e0040 dated 2014-10-28.
2. Please also include updated Data Definitions, Reviewer Guide, or programming details if they are new or have changed from e0019.



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 December 18, 2014 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 April 29, 2015.

If you have any questions, please contact me at (240) 402-8443.

Sincerely,

Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/PPMS

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