From: Thompson, Edward
Sent: Monday, December 22, 2014 2:54 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:

On page 26 of the Immunogenicity Risk Assessment submitted in e0040 dated 10/28/2014, the report includes a reported adverse event of anti-factor IX positive binding. Please explain why this instance of anti-factor IX positive binding was reported (listed as possibly related) and the other 17 conversions were not reported. Is there a clinical or laboratory difference or manifestation that differentiates this case from the others?

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 31, 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/RPMS