From: Thompson, Edward
Sent: Tuesday, December 16, 2014 3:11 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 provide FDA 510(K) number, manufacturer, product specification and product label for the LUER-LOK Administration Syringe. Please also submit a representative certificate of conformity and a drawing of the LUER-LOK administration syringe if they are not contained in the product specification document of the syringe. For your response preparation, you may refer to Section 3.2.R of your original BLA submission (dated 03/30/2012) for this information request (e.g., refer to the information provided for vial adapter and infusion set in the original BLA submission.

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 January 15, 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 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