

**From:** Thompson, Edward  
**Sent:** Tuesday, December 16, 2014 10:28 AM  
**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 update and submit Section 3.2.R Regional Information for the new kit presentation that includes a 20 ml Luer Lock Administration Syringe for review.



[125426.0.PDF](#)

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.

Please send me an acknowledgment message 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/PPMS

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