

From: Pracht, Leigh
Sent: Monday, April 21, 2014 11:32 AM
To: Steve McGregor (smcgregor@ebsi.com)
Subject: Information Request STN 125426/0 04212014

Importance: High


Our Reference: STN 125426/0

Cangene Corp
Attention: Mr. Steve McGregor
April 21, 2014
Sent by email


Dear Mr. McGregor:

We are reviewing your January 27, 2014 resubmission to your biologics license application (BLA) for Coagulation Factor IX (Recombinant). We determined that the following information is necessary to continue our review:

1. (b) (4)

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3. (b) (4)

A large rectangular area of the document is redacted with a solid gray fill, obscuring the text under item 3.



Please submit your responses as amendments to this file by May 5, 2014.

If you have any questions, please contact me at (301) 827-6116.

Best regards,

Leigh A. Pracht

Regulatory Project Manager
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