

**From:** Pracht, Leigh  
**Sent:** Monday, April 07, 2014 8:28 AM  
**To:** Steve McGregor (smcgregor@ebsi.com)  
**Cc:** Steve McGregor (smcgregor@Cangene.com)  
**Subject:** Information Request: BLA 125426/0.18 (Serial 0019)

**Importance:** High

Our Reference: STN 125426/0

Cangene Corp  
Attention: Mr. Steve McGregor  
April 7, 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. For documents in Sections 2.5 and 2.7 of Amendment 18 (Serial 0019), please provide in electronic Microsoft Word format redlined versions that track changes back to the same documents in the original submission.
2. Please expand the Summary of Major Changes in the cover letter of Amendment 18 (Serial 0019) to include changes made in Section 5. Please include the changes that were made to the electronic datasets.

Please submit your response to item #1 of this request by April 14, 2014, and your response to item #2 of this request by April 21, 2014 as amendments to this file.

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

*Best regards,*

***Leigh A. Pracht***

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