

From: Pracht, Leigh
Sent: Monday, April 21, 2014 5:18 PM
To: Steve McGregor (smcgregor@ebsi.com)
Cc: akennedy@ebsi.com
Subject: STN 125426/0 IR #2 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. With regard to response to CR item 4, you have provided Table 17 which lists several of the analytical methods for in-process monitoring. This table does not contain other analytical methods which are used for in-process testing and are described in Section 3.2.S.4.1 of your application. Please list in a revised Table 17 all of the analytical methods employed for in-process testing, including, but not limited to that for (b) (4)
2. With regard to the in-process controls for the (b) (4), we requested in item 5a of the CR letter, that you express the Acceptance Limits for the (b) (4). In your response dated 28 January, 2014, you included the (b) (4) (b) (4), but did not express the data in (b) (4). Please submit the data in (b) (4)

With regard to the in-process controls for the (b) (4) process steps (CR letter, item 5a), we requested that you (b) (4). Your response to this item, dated 28 January, 2014, does not include the (b) (4). Please submit the data in (b) (4). The use of (b) (4)

3. (b) (4) however, should be (b) (4) and the manufacturing process narrative should also include the activity units by which final product vials are filled. With regard to the in-process controls for the (b) (4), we requested in item 5c of the CR letter that you provide the

(b) (4) (supported by the process validation study). You provided information about th (b) (4) based on study F90-CR-030, but you did not support the (b) (4) information with a process validation study. Please include in your response the validation study for the (b) (4)

Please submit your responses as amendments to this file by April 30, 2014.

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

Best regards,

Leigh A. Pracht

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