From: Pracht, Leigh
Sent: Monday, April 28, 2014 4:57 PM
To: Steve McGregor (smcgregor@ebsi.com)
Subject: STN 125426/0 IR 04282014

Importance: High

Our Reference: STN 125426/0

Cangene Corp
Attention: Mr. Steve McGregor
April 28, 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) Regarding (b)(4) testing at (b)(4):

   - We have reviewed your response to the item 24a of the February 1st action letter issued in 2013. It is unclear from your response what (b)(4) limit you use for test results to determine if the (b)(4) testing is "passed or failed". Please comment and indicate the limit for pass/fail.

   - In the January 27th, 2014 submission, on page 4 of Section "3.2.P.3.3 Manufacturing Process and Process Controls" (manuf-process-and-controls.pdf), you state that (b)(4) testing has been removed from commercial specifications. Please provide justification for removing the (b)(4) testing from commercial specifications.

2) Regarding (b)(4) test method validation at (b)(4):

   You indicate in your response to our complete response item 25 that the validation of the integrity testing ((b)(4)) will be completed in early 2014. Please provide results of this validation along with the associated validation protocol in an amendment to the file if available. If not available at this time, please provide a request to submit this information as a post-marketing commitment (PMC) submission final study report. Please provide your PMC submission date**.**

3) We note that Batch Record (b)(4) is provided in the January 27th 2014 submission for a DS lot manufactured with the modified process, but there is no batch record submitted for DP lot manufactured from this post-change DS lot (DP Lot# (b)(4)). Please submit the batch record for DP lot (b)(4) along with a summary of deviations occurred during this DP lot manufacturing.

Please submit your responses as an amendment to this file by May 20, 2014.

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

Best regards,

Leigh A. Pracht
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