From: Thompson, Edward
Sent: Monday, March 16, 2015 2:49 PM
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 are providing the following comments and request for additional information to continue our review:

1. On March 12, 2015 you provided us with a revised SOP for the qualification of (b) (4) lots used for the bench (lab) scale (b) (4) (RAW-065-01.6). The revised version indicates that the testing applies to (b) (4) The study design and qualification criteria (Section 7 of the SOP) defines that (b) (4) Moreover, you described in Section 8 Qualification Criteria and Performance Targets, that if (b) (4)

   We found the modifications to the SOP to be partially acceptable, but we request the following clarifications:

   a. Please describe in the SOP how you will handle a situation in which not all the testing results can be evaluated because of a lack of material. The SOP is silent regarding cases where a minimum amount of material from (b) (4) could not be obtained successfully, as occurred earlier for the runs described in the (b) (4) lot (b) (4) (Table 3 Comparison of Bench Scale (b) (4) Qualifications to Manufacturing-Scale Campaigns in Appendix 3 in response Seq. 40). Please amend the amount of material that is needed to be retrieved from each sample to meet minimum requirements (Table 2 of the revised SOP).

   b. Regarding Section 8 Qualification Criteria and Performance Targets, please clarify what is meant by "an assignable cause is not identified" that will still allow a (b) (4) lot to be qualified, and detail the procedure that will be taken to come to this conclusion.

Please submit your response to this information request as an amendment to this file by March 20, 2015 referencing the date of this request.

The action due date for this file is April 29, 2015.

If you have any questions, please contact me at (240) 402-8443.

Sincerely,

Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/RPMS