**From:** Thompson, Edward
**Sent:** Friday, January 09, 2015 8:08 AM
**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 determined that the following information is necessary to continue our review:

1. The rationale for the upper limit of the end of shelf life specification of the (b) (4) is acceptable. However, please include the stability data from the (b) (4) 500 IU/vial DP data (Figure 2 and Table 2 in "response-to-fda-request-dated-november-4") and the paragraph "Rationale for (b) (4) End of Shelf Life Specification" in section 3.2.P.5.6 in the CTD component of the application, because this information is critical for the justification of this limit.

2. All updated results from clearance studies for the following process related impurities: (b) (4), CHO HCP, (b) (4) and the spiking test results for the process-related impurities (including Chinese Hamster Ovary Host Cell Protein (CHO HCP)) should be submitted to the CTD component of the application.

3. A time limit of (b) (4) has been established for the (b) (4) based on review and assessment of (b) (4) historical manufacturing-scale data including two IB1001 process validation conformance campaigns. You have only partially amended the CTD component of the application accordingly; specifically the data in Table 9 in section 3.2.S.2.5 should be amended.

4. In your response to IR #7 from November 18, 2014, you have provided a new table (Table 5) with the calculated potency regarding all manufacturing lots since 2009 using the IU/vial units. Please amend the CTD component of the application accordingly.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by January 26, 2015 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

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

Please send an acknowledgement message for receipt of this request.

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

Sincerely,

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