

**From:** Pracht, Leigh  
**Sent:** Tuesday, May 01, 2012 11:42 AM  
**To:** 'Tung Koh'  
**Subject:** Information request re: STN 125426/0  
Our Reference: BL 125426/0

Inspiration Biopharmaceuticals, Inc.  
Attention: Ms. Tung Koh  
May 1, 2012  
Sent by email

Dear Ms. Koh:

We are reviewing your April 5, 2012 biologics license application (BLA) for Coagulation Factor IX (Recombinant). We are providing the following comments and requests for additional information to continue our review:

Bioresearch Monitoring

1. This application only contains investigator CVs and does not have any document to link the investigator to a particular site or to identify the site numbers. We require a list that shows the investigator's name, the institution's name, full address, and telephone number, the site number, and the number of subjects at each site.
2. The datasets are in a list form and are not able to be manipulated in any way. Since this is a small study, you may submit the data tables in Excel. Each table should list the subject by ID and site number, if the site is not identifiable in the subject's ID.

Clinical Pharmacology:

3. Please provide 2-sided 90% confidence interval on log transformed AUC.
4. Please provide log based 10 (not natural log (ln)) individual concentration-time plots of all 32 subjects in the PK study.
5. Please provide log based 10 mean concentration-time plots for single and repeat dose study.
6. Please provide individual concentration-time data for both single and repeat dose studies. If you have already provided these data please indicate the location.

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 responses to this information request as amendments to this file by May 11, 2012 for the Bioresearch Monitoring responses and May 31, 2012 for the Clinical Pharmacology

responses 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.

The action due date for this file is February 4, 2013.

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

Sincerely,

*Leigh A. Pracht*

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