

From: Pracht, Leigh
Sent: Monday, October 15, 2012 12:37 PM
To: Tung Koh
Subject: STN 125426/0 Information Request 15-Oct-2012
Our Reference: BL 125426/0

Inspiration Biopharmaceuticals, Inc.
Attention: Ms. Tung Koh
Oct 15, 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:

1. Some information about withdrawn patients is given in Appendix 16.2.1 and in sections 11.4 of the study reports. Please provide complete narratives for all patients who withdrew from the study or were lost to follow-up, including the reasons and circumstances why they withdrew.
2. The new table ACHOBAT submitted as part of amendment 6 does not use the same field name for the patient identifier field as the rest of the data submission, i.e. ACHOBAT uses PTID while the rest of the file uses ID. Please resubmit the ACHOBAT file using the field name ID to be consistent with the rest of the file and to properly work with internal FDA data structures.
3. In the new table ACHOBAT, field for CHO results (CHORESULT) typically gives just a two digit number which is not a proper numerical value. Please resubmit the table so that the numbers are given in proper numerical or scientific notation.
4. In the AE table, some rows are missing data. For instance, rows 23 and 24 are missing data in the AEOUT, AEREL, AESER, and AESEV fields. Also, some AEENDT and AEENTM are missing. Also in this table, in the AESTTMC and AEENTMC fields there are multiple "K"s. Please explain or revise this table to include all data.
5. Please submit to the BLA the following documents from IND 13551 Amendment 61, or please provide their location in the documents already submitted to the BLA:
 - a. Response to information request
 - b. Attachments 3-6

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 November 15, 2012 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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