M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE December 6, 2012

FROM Carla Jordan, Bioresearch Monitoring, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH Patricia Holobaugh, Bioresearch Monitoring Branch Chief, HFM-664

TO Roman Drews, Chair, BLA Committee, HFM-392

SUBJECT Bioresearch Monitoring Final Review Memo
STN: 125426/0
Product: Recombinant Coagulation Factor IX (IB1001)
Sponsor: Inspiration Biopharmaceuticals

SUMMARY STATEMENT

CBER Bioresearch Monitoring (BIMO) issued five high-priority inspection assignments covering seven clinical investigators. The BIMO inspections did not reveal any problems that would impact the data submitted in the BLA.

BACKGROUND

Five clinical investigator inspections were performed in support of this BLA. Study subject enrollment and previous inspection history were among the factors used to select the inspected sites. The inspections focused on specific questions concerning the study protocol and the comparison of data submitted in the BLA to source documents.

STUDY TITLE

Protocol IB1001-01
Phase I, II/III Pharmokinetic and Outcome Study of Inspiration's Recombinant Factor IX Product, IB1001, in Subjects with Hemophilia B

CLINICAL INVESTIGATOR SITES

Location	Site #	# of Subjects	FDA 483
Ramat Gan, Israel	40	12	No
Pune, India	90	3	No
Pune, India	91	3	No
Chicago, IL	71	5	Yes
Los Angeles, CA	74	10	No

FINANCIAL DISCLOSURE

The Clinical Investigator Compliance Program directs the FDA investigator to ask the clinical investigator if and when he/she disclosed information about his/her financial interests to the sponsor and also the interests of any sub-investigators, spouse(s) and dependent children, and if and when the information was updated. The seven clinical sites provided copies of the financial disclosure forms to the FDA investigators. The information submitted to the BLA was verified for each investigator.

SPONSOR ISSUES

None noted.

NOTEWORTHY INSPECTIONAL FINDINGS

1. Failure to ensure the study was conducted in accordance with the general investigational plan and protocol:

Site 71: Site did not report a serious adverse event to the Sponsor/IRB by the end of the next business day, as required by the protocol.

BIMO ADMINISTRATIVE FOLLOW-UP

BIMO issued letters to all clinical investigators.

Please contact me at (301) 827-6348 if you have any questions about this memo or any aspect of bioresearch monitoring.

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Carla V. Jordan
Consumer Safety Officer

Cc:

Paper Copy
HFM-664 Access/CHRON

Electronic Copy (FYI)
EDR IND 13551 memo folder
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History
Draft: Jordan: 12/05/2012
Reviewed: Holobaugh: 12/6/12