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

DATE August 10, 2012

FROM Carla Jordan, Bioresearch Monitoring Branch, 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, HFM-392, Chair, BLA Committee
Leigh Pracht, HFM-380, RPM, BLA Committee

SUBJECT Bioresearch Monitoring Mid-Cycle Review
BLA: STN 125426/0
Sponsor: Inspiration Biopharmaceuticals
Product: Recombinant Factor IX Product (IB1001)

Bioresearch Monitoring clinical investigator inspection assignments were issued on June 1, 2012 and June 4, 2012 for the following sites:

Site	**# Subjects**	**FDA Form 483**	**EIR Received**
Rush University Medical Center, Chicago, IL #71	5	Pending	Pending
Hemophilia Treatment Center, Orthopaedic Hospital, Los Angeles, CA #74	10	No	No
Israel National Hemophilia Center, Sheba Medical Center, Israel #40	12	Pending	Pending
Jehangir Clinical Development Centre, India #90	3	Pending	Pending
Sahyadri Specialty Hospitals #91	3	Pending	Pending

To date, one inspection has been completed with no FDA Form 483 being issued. However, the Establishment Inspection Report has not yet been received at CBER. The remaining inspections are pending. I will inform the committee about the results of the inspections as soon as they are available. Should you have any questions about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 301-827-6348.

Carla V. Jordan
Consumer Safety Officer

cc:

Paper Copy
HFM-664 Access/Chron

Electronic Copy (FYI)
EDR IND 13551 memo folder
HFM-650 Gilliam Conley
HFM-392 Roman Drews
HFM-380 Leigh Pracht
HFM-392 Stephanie Omokaro
HFM-392 Irwin Feuerstein

Draft: Jordan: 8/10/12
Reviewed: Holobaugh: