

Bioresearch Monitoring "Mid-Cycle" Review Report - RECOTHROM

MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE: June 12, 2007

FROM: Janet White, 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, HFM-392, Chair, BLA Committee

SUBJECT: Bioresearch Monitoring "Mid-Cycle" Review Report

BLA/STN 125248/0

Product: Recombinant Human Thrombin (rhThrombin)

Sponsor: ZymoGenetics, Inc., Inc.

Three clinical investigator inspection assignments were issued on February 22, 2007. The BIMO Inspection assignment included specific questions for the following protocol: *499E01 - A Phase 3, Randomized, Double-Blind, Controlled, Comparative Efficacy and Safety Study of Topical Recombinant Human Thrombin (rhThrombin) and Thrombin-JMI (Bovine Thrombin) in Surgical Hemostasis*. The assignments included instructions to compare data from the BLA and the source documents.

CLINICAL INVESTIGATORS

483 PRELIMINARY CLASSIFICATION

Yuri S. Genyk, M.D.
USC Healthcare Consultation Center
Los Angeles, California

No NAI

James W. McNeil, M.D.
Vascular Surgery Associates
Baton Rouge, Louisiana

No NAI

Kenneth L. Renkens Jr., M.
Indiana Spine Group
Indianapolis, Indiana

Yes VAI

PRELIMINARY INSPECTIONAL FINDINGS

The preliminary inspectional finding for Dr. Renkens' site included the following one FDA-483 item: failure to conduct the investigation in accordance to the investigational plan. This finding involved baseline conditions, adverse events, and concomitant medications that were noted in the subject study files and nmedical records, but which were not included on the case report forms or included in the study data reported to the FDA by the sponsor. It should be noted that the above finding for Dr. Renkens is solely from the FDA-483 issued and has not been verified by the BIMO branch through review of the inspection report and exhibits. BIMO has not reviewed the inspection report and exhibits for Dr. McNeil.

BIMO issued an NAI letter to Dr. Guy Young.

Should you have any questions or comments about this memorandum or any aspect of Bioresearch Monitoring, please contact me at (301) 827-1948.

/Janet White/

Janet White

Consumer Safety Officer

Cc:

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