

MEMORANDUM

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

DATE October 15, 2013

FROM Erin McDowell, Bioresearch Monitoring Branch, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

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

THROUGH Gilliam Conley, Director, Division of Inspections and Surveillance,
HFM-650

TO Michael Kennedy, HFM-345, Chair
Edward Thompson, HFM-380, RPM
Mitchell Frost, HFM-392, Clinical Reviewer

SUBJECT Bioresearch Monitoring Summary
SPONSOR: Instituto Bioclon S.A. de C.V.
PRODUCT: Crotalidae Immune Fab2 Equine Injection
BLA: STN 125488/0

SUMMARY STATEMENT:

Three Bioresearch Monitoring (BIMO) inspections of clinical investigators were conducted in support of BLA STN 125488/0. The inspections revealed the investigational product accountability and disposition records were not clearly documented at one site.

BACKGROUND:

The sponsor submitted the BLA on March 16, 2013 for Anavip® is a Crotalinae (pit viper) equine immune F(ab')₂ antivenom whose indication for use is in the treatment of envenomation by Crotaline snakes.

The BIMO branch requested three clinical investigator inspections on May 22, 2013 covering one clinical study in support of the BLA. Information from the BLA was compared to source documents during the inspections. The inspections were conducted in accordance with FDA's Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators. The BIMO inspection assignments included specific questions for the following clinical study: A Comparison of Anavip® [Crotalinae (pit viper) equine immune F(ab)₂] and CroFab® (Crotalidae Polyvalent Immune Fab, ovine) in the Treatment of Patients with Crotalinae Envenomation: A Randomized, Prospective, Blinded, Controlled, Comparative, Multicenter Study (Protocol No. YA-C-02).

INSPECTIONS OF CLINICAL INVESTIGATORS AND OUTCOMES:

Site #	Study Site	Location	Form FDA 483 Issued	Inspection Final Classification
10	Loma Linda University Adventist Health Sciences Center	Loma Linda, California	No	NAI
16	Banner Good Samaritan Medical Center	Phoenix, Arizona	No	NAI
20	St. Joseph's Regional Health Center	Bryan, Texas	Yes	VAI

NAI=No Action Indicated; VAI=Voluntary Action Indicated.

SIGNIFICANT INSPECTIONAL FINDINGS:

The inspection at Site#20 revealed that the investigational product accountability and disposition records were not clearly documented. The inspections at Site#10 and Site#16 revealed no deviations from applicable regulations. No sponsor or monitoring issues were noted at these sites.

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/or interests of any sub-investigators, spouse(s) and dependent children, and if and when the information was updated. All inspected sites had copies of the financial disclosure forms for the clinical investigators and sub-investigators.

ADMINISTRATIVE FOLLOW-UP:

Letters were issued to the clinical investigators after complete review of the inspection reports. Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 301-827-2590.

Erin McDowell
Consumer Safety Officer

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