

MEMORANDUM

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

DATE November 24, 2014

FROM Colonious King, Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Telephone: 240-402-8759 Fax: 301-595-1304

THROUGH Patricia Holobaugh, Chief, Bioresearch Monitoring Branch

THROUGH Gilliam Conley, Director, Division of Inspections and Surveillance

TO Robert Fisher Chair, Review Committee
Thomas Maruna RPM
Leland Ross Pierce Clinical Reviewer

SUBJECT Bioresearch Monitoring Discipline Review Memo
BLA/STN: 125562/0
IND: 11982
Sponsor: Cangene Corporation/ Emergent Solutions
Product: NP-015, Anthrax Immune Globulin Intravenous (Human),
Anthraxil

REVIEW SUMMARY

Bioresearch Monitoring (BIMO) domestic inspection for a clinical investigator study site did not reveal problems that impact the data submitted in this Biologics Licensing Application (BLA).

BACKGROUND

A Clinical Investigator Inspection Assignment was issued for the clinical Pharmacokinetics (PK) study site in support of this BLA. There was only one study site for the clinical (PK) portion submitted in support of this BLA. Because clinical trials in a population intentionally exposed to inhalational anthrax are not ethical or feasible, the efficacy of NP-015 was assessed in two animal models in accordance to the Animal Rule, 21 CFR Part 601 (subpart H). The number of subjects selected for data verification represented 80 percent of subjects enrolled in the study.

The inspection was conducted in accordance with the FDA's Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators. The inspection assignment included specific questions related to the study protocol and verification of the pharmacokinetic assessment data submitted by the sponsor in the BLA.

PROTOCOL AUDITED

Safety and Pharmacokinetics of Anthrax Immune Globulin Intravenous (Human), NP-015, in Healthy Volunteers. (Protocol AX-001)

The table below summarizes the inspection results:

Site Number	Study Site	Location	Enrolled Subjects	483 Issued	Classification
001	MDS Pharma Services	Lincoln, Nebraska	92	No	NAI

NAI = No Action Indicated

FINANCIAL DISCLOSURE

The Clinical Investigator Compliance Program directs the FDA investigator to ask the clinical investigator if and when s/he disclosed information about her/his financial interests to the sponsor and/or interests of any sub-investigators, spouse(s) and dependent children including if and when the information was updated. The inspected study site had a copy of the financial disclosure forms on hand for the clinical investigator and sub-investigators.

INSPECTIONAL FINDINGS

Sponsor/Monitor Issues

There were no sponsor/monitor issued identified at the study site audited.

Clinical Investigator (CI) Study Site Issues

Study Site 001: A Form FDA 483 was not issued at close of this inspection and the inspection was classified as NAI. A review was conducted of testing records, regulatory binders, study specific standard operating procedures, and general study conduct. In addition, source documents were reviewed and the information contained was compared to the data tables submitted by the sponsor in the application. No discrepancy was found between source documents at the site and the data submitted by the sponsor in the application.

BIMO ADMINISTRATIVE FOLLOW-UP

An information letter was issued for the study site inspected. Please contact me should you have any questions about this memo or any aspect of Bioresearch Monitoring.

Colonious King
Consumer Safety Officer