TABLE OF CONTENTS

SUMMARY

A directed Good Laboratory Practice (GLP) FY 11 inspection (BIMO Control Number #2011-00 I) of this non-clinical laboratory was performed in accordance with an assignment issued by the Pre-Market Compliance and Administrative Actions Team, HFV-234, Division of Compliance, Center for Veterinary Medicine (CVM). FACTS Assignment #1240159 was designated. Compliance Program Guidance Manual (CPGM) 7348.808, Good Laboratory Practice (Non-Clinical Laboratories) and assignment/special instructions provided guidance. **Attachment 4** consists of Center/NYK-DO correspondences in conjunction with the assignment that document inspectional intent/depth and special instructions as they pertain to this firm.

It was requested by CVM that this inspection not be pre-announced.

This firm has no previous violative FDA inspectional history and the previous inspection, performed on 8.21-23.2006, was NAI.

CVM specifically requested determination of compliance with GLP regulations for analytical work the firm performed/contracted out in connection with four studies for which data was submitted to FDA. The submissions are currently under review to support premarket approval of either an abbreviated new animal drug application (ANADA) or new animal drug application (NADA), under section 512(b) of the Federal Food, Drug, and Cosmetic Act. Application and study information is as follows:

Application #1

(b) (4)

Application # 2

(b) (4)

Application #3

(b) (4)

At the close of the current inspection, an Inspectional Observations (FDA-483) (**Attachment 3**) was issued to the firm's management regarding observed noncompliance with GLPs. Significant deficiencies are as follows:

- Testing facility management failed to assure that all personnel clearly understood the functions they were to perform.
- The study director failed to assure that all applicable GLP regulations were followed.
- The quality assurance unit did not monitor each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls were in conformance with FDA GLP regulations.
- Not all consulting laboratories, contractors, or grantees were notified that the study must be conducted in compliance with FDA GLP regulations.
- The study director failed to assure that all experimental data, including observations of unanticipated responses of the test system, were accurately recorded and verified.
- The testing facility does not have written standard operating procedures setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study.

- Not all nonclinical laboratory studies were conducted in accordance with the protocol.
- Not all individuals engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have education, training, and experience, or combination thereof, to enable that individual to perform assigned functions.
- Testing facility management failed to assure that all test and control articles or mixtures had been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.
- Archives failed to provide for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports.

The firm's management was informed that they have the opportunity to respond to the FDA 483 observations, and observations discussed with management, in writing, within 15 business days to the NYK-DO district office/District Director and that their response will be considered by the Agency before determining action.

ADMINISTRATIVE DATA

Inspected firm:	Liberty Research Inc.
Main Offices and	170 Route 17c
Colony Site:	PO Box 107
	Waverly, NY 14892-0107
Research/Study	1479 Talmadge Hill South
Location:	Waverly, New York 14892
Mailing address:	170 Route 17c
	PO Box 107
	Waverly, NY 14892-0107
Phone:	607-565-8131
FAX:	607-565-7420
Website:	http://www.lriresearch.com/Home.aspx
Email:	wmwaring@libertyresearch.biz
Dates of inspection:	2/15/2011, 2/16/2011, 2/17/2011, 2/18/2011, 2/21/2011, 2/22/2011, 2/23/2011, 3/1/2011
Days in the facility:	8
Participants:	Kathryn A. Nagy, Investigator
	Joanne M. Schlossin, Investigator

On the initial date of our inspection, our credentials were displayed to and the Notice of Inspection (FDA 482) (**Attachment 1**) was issued to Michael J. Garrison, General Manager, in the absence of William M. Waring, President and CEO. Mr. Garrison identified himself as the most responsible individual at the 170 Route 17c, Waverly, NY/main office site and at the initiation of our inspection. The purpose of our inspection was discussed. Mr. Waring joined us later in our inspection.

On 2.18.11, we issued an additional Notice of Inspection (FDA 482) (**Attachment 2**) to Tanya L. Shaffer, Study Coordinator and Interim Facility Manager for the firm's primary research site located at 1479 Talmadge Hill South, Waverly, NY. The research site is physically distinct and located approximately 4 miles from the 170 Route 17c, Waverly, NY/main office site.

Investigator Schlossin was present for all dates of the inspection except for closeout on 3.1.11. Due to inclement weather, the final date of the inspection/closeout was postponed until 3.1.11.

In addition to Mr. Garrison and Ms. Shaffer, we were accompanied at various times during our inspection by the following individuals:

Beth Bell	Director of Research
David M. Houser	Colony Manager
(b) (6) (b) (6)	Sr. Study Coordinator/Research Marketing Associate
Tina L. Yanchis-Kirby	Quality Assurance Director
William M. Waring	President and CEO

The above individuals provided facility tours, relevant inspectional information, documentation and responded to specific questions during the course of the inspection as their responsibilities and/or knowledge dictated.

On 3.1.11, during closeout, I issued the Inspectional Observations (FDA 483) to Michael J. Garrison, General Manager, in the physical absence of William M. Waring, President and CEO.

This inspection report was written by Investigator Nagy.

HISTORY

The firm was incorporated in the state of New York in 1989. William M. Waring is President and CEO; the Chairman of the Board is Joseph G. Wortley, Jr. Mr. Wortley is not present at the Waverly, NY sites and maintains his offices at 20 SE 3rd Street, Boca Raton, FL 33432.
The majority of this firm's business involves the breeding of cats and dogs for sale as research subjects under the auspices of the U. S. Department of Agriculture. According to the firm's website "Liberty Research, Inc. (LRI) is a USDA Class A licensed dealer dedicated to providing a reliable supply of high quality, barrier raised, purpose-bred, Antibody Defined (AD) Felines and Canines for use in Research. Offering a variety of services and products, Liberty maintains its status as a leading breeder of premium quality Antibody Defined felines and canines and also as a provider of research services. Our Main Site houses our colony production facility and we have a second site with a separate facility dedicated to research. The Research site is approximately 4 miles from the Main Site and is constructed and operated according to Animal Bio-Safety Level 2 containment guidelines as outlined by the National Institute of Health and the Center for Disease Control. The facility consists of 10 buildings with a functional necropsy, laboratory area, two minor procedures rooms and an office on site. The HVAC system is a one-pass air system with negative pressure to the

animal rooms. Temperature is controlled and maintained at the room level. LRI offers a wide range of contract research services.... Whether your study is a pilot study or if your requirements include GLP, CVM, EU or Japanese regulatory guidelines, our qualified staff is prepared to meet your needs and time constraints. Studies performed at LRI include but not limited to: Pilot Studies, Efficacy Studies, Safety Studies, Vaccine Trials, Duration of Immunity, Reversion to Virulence, Shed & Spread of Virus, Reproduction Studies, Animal Bio-Safety Level 2 challenges and Behavioral Toxicity. In addition to the technical expertise of our staff, we are willing to provide facilities on a priority basis. Liberty Research, Inc. also provides technical services including: surgical services such as ovariohysterectomies, castrations, hysterectomies and placement of vascular ports.
LRI provides canine and feline whole blood, fresh frozen plasma and packed red cell products to the research community. In addition, we can provide tissue products prepared to your specifications. Our AD derived blood and tissue products are superior for cell culture."

Normal office hours for this firm are approximately 8:00 am to 5:00 pm Monday through Friday. Animal care personnel work (b) (6) as needed and research personnel are present on varying schedules depending on study protocol requirements/additional responsibilities.

Official correspondence should be addressed to:

William M. Waring, President and CEO
Liberty Research Inc.
170 Route 17c
PO Box 107
Waverly, NY 14892-0107

INDIVIDUAL RESPONSIBILITY

Current LRI organizational charts are included as **Exhibit 4**.

The following table illustrates individual responsibilities for firm representatives predominantly involved in this investigation/the reviewed GLP studies:

NAME	TITLE	DIRECT REPORT	RESPONSIBILITIES	RELATED EXHIBIT
William M. Waring	President and CEO	Joseph G. Wortley, Jr, Chairman of the Board	Authority over all day to day operations of the firm, including hiring and firing of employees, capital expenditures, and approval of standard operating procedures	Job Description, **Exhibit 56**

Michael J. Garrison	General Manager	William M. Waring, President and CEO	Supervision of the animal colony, facility technicians, maintenance, sales, training and IACUC Chair	Job Description, **Exhibit 57**
Beth Bell, DVM, Ph.D	Director of Research	William M. Waring, President and CEO	Contract personnel, planning, resources, quality control, compliance, timelines	Job Description, **Exhibit 58**
(b) (6) (b) (6)	Sr. Study Coordinator/ Research Marketing Associate	William M. Waring, President and CEO	All procedures in support of research projects/study conduct, senior management responsibilities, contract research, budgets, design and preparation of protocols and reports, sponsor communication	Job Description, **Exhibit 5**
Tina L. Yanchis-Kirby	Quality Assurance Director	William M. Waring, President and CEO	Assuring that non-clinical studies comply with the GLP regulation and other applicable regulations, including auditing study records, maintaining the records archive and maintaining personnel training records. Also performs employee training.	Job Description, **Exhibit 6**
Tanya L. Shaffer	Study Coordinator and Interim Site Manager for the Talmadge Hill South research site	William M. Waring, President and CEO and (b) (6) (b) (6) Sr. Study Coordinator/Research Marketing Associate	Procedures in support of research projects/study conduct and supervision of the facility technicians, maintenance… as applicable to the Talmadge Hill South research site	Job Description, **Exhibit 7**

BACKGROUND

Background information was provided by Center representatives and is documented in pages 5-13 of **Attachment 4**. CVM noted what appeared to be significant noncompliance at this testing facility. Additionally, a number of contractors appeared to be noncompliant with GLPs though the extent of the noncompliance could not be determined based on the reports received by CVM.

GLP INSPECTION

A directed GLP inspection was conducted in accordance with CP 7348.808, Good Laboratory Practice (Non-Clinical Laboratories); assignment/Center special instructions provided guidance as well.

During our inspection, we provided firm representatives with the following document:

- A copy of "Guidance for Industry Good Laboratory Practices Questions and Answers" DHHS/ORA, June 1981 (Minor editorial and formatting changes made December 1999 & July 2007

General documents collected in conjunction with the CPGM and Center assignment are as follows:

Master Schedule as of January 2011	**Exhibit 8**
Master Schedule as of December 2010	**Exhibit 9**
Master Schedule as of December 2009	**Exhibit 10**
Master Schedule as of December 2005	**Exhibit 11**
Facility Licenses and Certifications	**Exhibit 12**
List of Sub-contractors used by LRI	**Exhibit 13**
LRI IACUC Members	**Exhibit 14**
LRI IACUC SOP FAC.1100.002	**Exhibit 15**
LRI IACUC Meeting Minutes for August 26, 2010	**Exhibit 16**
LRI IACUC Meeting Minutes for June 28, 2010	**Exhibit 59**
LRI IACUC Meeting Minutes for February 16, 2010	**Exhibit 17**
LRI IACUC Meeting Minutes for December 10, 2009	**Exhibit 60**
LRI IACUC Meeting Minutes for September 29, 2009	**Exhibit 18**
LRI IACUC Meeting Minutes for July 29, 2009	**Exhibit 19**
LRI IACUC Meeting Minutes for February 9, 2009	**Exhibit 20**
LRI IACUC Meeting Minutes for December 16, 2008	**Exhibit 61**
LRI IACUC Meeting Minutes for June 25, 2008	**Exhibit 21**
LRI IACUC Meeting Minutes for March, August, September, October and November, 2008	**Exhibit 22**
LRI IACUC Review & Approval for LRI Study No: 07.0446.072	**Exhibit 23**
LRI IACUC Review & Approval for LRI Study No: 04.2520.023	**Exhibit 24**
LRI IACUC Review & Approval for LRI Study No: 08.2520.031	**Exhibit 25**
LRI SOP Index	**Exhibit 26**
LRI SOP Facility Management Standard Operating Procedures FAC 1100.001	**Exhibit 27**
LRI SOP Responsibilities of the Quality Assurance Unit QAU.2900.001	**Exhibit 28**
LRI SOP Project Initiation PRJ.2200.001	**Exhibit 29**
LRI SOP Sponsor's Protocol PRJ.2200.003	**Exhibit 30**
LRI SOP Training FAC.1100.003	**Exhibit 31**
LRI SOP Study Data Collection DAT.2700.002	**Exhibit 32**
LRI SOP Accounting and Data Records TCA.2300.002	**Exhibit 33**

LRI SOP Inspections QAU.2900.002	**Exhibit 34**
LRI SOP Record Keeping QAU.2900.003	**Exhibit 35**
LRI SOP Auditing Study Data and Reports QAU.2900.005	**Exhibit 36**
LRI SOP Data Collection and Record Keeping COL.3100.006	**Exhibit 37**
LRI SOP Archives ARC.1300.001	**Exhibit 38**
LRI SOP Assignment of Project Numbers PRJ.2200.002	**Exhibit 39**
LRI SOP Documenting Protocol Deviations PRJ.2200.007	**Exhibit 40**
LRI SOP Test Article Handling TCA.2300.001	**Exhibit 41**

ORGANIZATION AND PERSONNEL

This firm employs approximately (b) (4) people, encompassing both the 17C and Talmadge Hill South sites. Employee positions include animal care technicians, drivers, research technicians, study coordinators, staff veterinarian and study directors. Reporting relationships are documented in the current LRI organizational charts included as **Exhibit 4.**

The firm's quality assurance unit consists of one individual:

Tina L. Yanchis-Kirby	Quality Assurance Director	Job Description, **Exhibit 6**

The position of Quality Assurance Associate is currently vacant.

LRI SOP, Responsibilities of the Quality Assurance Unit QAU.2900.001, is included as **Exhibit 28.**

The QAU maintains the firm's Master Schedule and includes all studies performed by the firm, most of which are not subject to the Good Laboratory Practice regulation. Master Schedules for 2011, 2010, 2009 and 2005 are attached as **Exhibits 8-11** respectively. The master schedule includes the client (sponsor) number, study number, study director, study title, test system, regulations under which the study is to be conducted, nature of study/method of application, test article, test article receiving date, test article ID number, study initiation/ completion dates, and status. **Exhibit 55** is the key to the Master Schedule sponsor ID coding. The studies subject to 21 CFR Part 58 are differentiated from non-GLP studies, as in the case of documents collected during our inspection, by Ms. Yanchis-Kirby by hand with a highlighter.

Files are maintained for individual employees that contain resumes/CVs, job description and training. We reviewed employee files for the following firm employees:

- (b) (6) (b) (6) Study Coordinator
- Tina L. Yanchis-Kirby, QAU
- Tanya L. Shaffer, Study Coordinator
- (b) (6) , Technician
- (b) (6) , Technician
- (b) (6) , Technician

See **DISCUSSION WITH MANAGEMENT** for items discussed at closeout with firm representatives in conjunction with employee GLP training.

LRI SOP, Training FAC.1100.003, is included as **Exhibit 31.**

We observed employees working at the 17C colony and Talmadge Hill South study complex sites and did not note any deficiencies related to SOPs, health precautions, appropriate clothing or record keeping procedures.

The firm does not use any computerized data collection systems, therefore we did not review computer validation or training procedures.

Although there is some SOP guidance on project initiation (**Exhibit 29**), firm representatives stated that the signed protocol is considered by LRI to represent contractual responsibilities/acceptance between LRI and any sponsor.

FACILITY

Exhibit 42, page 1 is a site diagram of the 17 C colony facilities. Buildings are designated for purposes of animal breeding, storage of animal feed and bedding, receipt of animals purchased from outside vendors, non-clinical trial performance, animal grow-out and acclimation, necropsy and surgeries. The firm's main offices, an employee break room, storage area and the firm archives are housed at this site as well.

Exhibit 42, page 2 is a site diagram of the Talmadge Hill South study complex where any GLP studies are performed.

Test articles are received from the study sponsors and are held in a locked room in the main office building.

Each building is covered by its own air handling system and each animal room is equipped with its own thermometer and hygrometer. All rooms are on a (b) (4) cycle. Monitoring records are available for maintenance of the HVAC systems, monitoring of temperature and humidity in the animal rooms and monitoring of the light/dark cycle.

The firm utilizes equipment consistent with a facility performing research oriented operations including, but not limited to, refrigerators, freezers, incubators, thermometers, balances/scales, hygrometers, centrifuges, autoclaves and dosing and collection supplies.

Water is from the (b) (4) supply. A report is received (b) (4) from the (b) (4) showing test results for chlorine residual and total coliforms. The water is also tested for pesticides and PCBs. Onsite water treatment consists of (b) (4).

We examined animal rooms housing cats and dogs at both sites; animal care, general sanitation and housekeeping appeared to be acceptable.

ANIMAL CARE

The firm has an Institutional Animal Care and Use Committee (IACUC) which is chaired by Michael J. Garrison, General Manager. **Exhibits 14-25** are the IACUC member listing, SOP, meeting minutes and study approvals for reviewed studies, respectively.
The firm utilizes cats and dogs (beagles, collies, mini mongrels) for research purposes; only one species and one study are in a single room at one time.

Written SOPs are available relating to housing, receipt, identification, feeding and watering, disease, dosing, transportation, observation, randomization, euthanasia, necropsy, colony management, pest control and veterinary services.

Room maintenance records are posted on room doors and are used to document sanitation activities.

No pesticides are used in any areas housing animals. Insect electrocutors and box traps are used as needed. We did not note any evidence of pests in feed storage areas or study rooms.

Most animals used for testing at this facility are obtained from the firm's own breeding facilities and are under the care of a staff veterinarian. Study records include documentation of any treatments provided to the animals. All cats and dogs are identified with ear tattoos. Long haired dogs currently on study also had their ID numbers on collars in addition to the ear tattoos.

All animals are fed a species appropriate, nutritionally complete feed designed for laboratory/research animal purposes.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

Testing facility management failed to assure that all personnel clearly understood the functions they were to perform.

Specifically,

A. Protocols for the following studies state that these studies are to be performed in compliance with 21 CFR Part 58. However, both studies contain analyses not performed according to GLPs including serum analyses for all

vaccine titers, water analyses, blood and fecal analyses, gross necropsy, histopathology evaluations, slit lamp and indirect opthalmoscopy examinations and the manufacture and analysis of the test material.

(b) (4)

B. The firm's QAU does not monitor contractors utilized in the generation of study data.
C. The firm failed to notify all contractors utilized for data generation in their GLP studies that their services must comply with GLP regulations.
D. The study director failed to assure that all experimental data, including observations of unanticipated responses of the test system, were accurately recorded and verified.
E. The testing facility does not have adequate written standard operating procedures setting forth nonclinical laboratory study methods that are adequate to insure the quality and integrity of the data generated in the course of a study.

Reference: 21 CFR 58.31(f)

Supporting Evidence and Relevance:

Testing Facility Management, possessing the ultimate responsibility for ensuring that the facility operates in compliance with GLP requirements, failed to attend to its core responsibilities to remain GLP-compliant by not assuring that all personnel clearly understood the functions they were to perform in order to maintain compliance with the GLP regulations as evidenced in the following examples:

A. In the study entitled (b) (4) the Study Protocol states that the study is to be performed in compliance with 21 CFR Part 58. However, the study contains analyses not performed according to GLPs; use of non-GLP contractors is also documented in the protocol as well as in study correspondences obtained during the inspection.

GLP Statement: **Exhibit 1, page 7**
Use of Non-GLP contractors: **Exhibit 1, pages 5, 8, 20**
Exhibits 43, 44, 45

B. Management failed to assure that the QAU monitors any contractors utilized in the generation of study data.

No documentation of contractor monitoring

C. Management failed to assure that the firm notifies/ all contractors utilized for data generation in their GLP studies that contractor services must comply with GLP regulations.

No documentation of notification of contractors pertaining to GLP compliance.

D. In conjunction with the study entitled "(b) (4) ", management failed to assure

Exhibits 46, 47, 48

that all study data were accurately recorded and verified according to firm SOP for data collection for "data that will be considered necessary to fully document research studies", and evidenced by SOP and protocol deviations.

E. Management failed to assure that the testing facility has adequate written standard operating procedures setting forth nonclinical laboratory study methods that are adequate to insure the quality and integrity of the data generated in the course of a study for, including but not limited to, the following: Criteria for the determination of degree of severity of protocol and/or SOP deviations, Mitigation of study bias, Certification of Copies, Transfer of Study Data, Utilization of Contractors, Sponsor Responsibilities, Protocol training, QAU Evaluation of Contractors per GLPs. **Exhibit 26**

Discussion with Management:

It was explained to firm representatives that studies being conducted at this site are required to be in compliance with FDA GLP regulations and that all personnel clearly understood the functions they are to perform in order to maintain compliance with the GLP regulations. Firm representatives were cooperative, did not commit to the initiation/implementation of corrective actions and stated that a written response would be submitted to NYK-DO DD.

OBSERVATION 2

The study director failed to assure that all applicable GLP regulations were followed.

Specifically, protocols for the following studies state that these studies are to be performed in compliance with 21 CFR Part 58. However, both studies contain analyses not performed according to GLPs including serum analyses for all vaccine titers, water analyses, blood and fecal analyses, gross necropsy, histopathology evaluations, slit lamp and indirect opthalmoscopy examinations and the manufacture and analysis of the test material. The study director for these studies, failed to assure that all applicable GLP regulations were followed as they apply to the contractors utilized in the generation of study data.

(b) (4)

Reference: 21 CFR 58.33(e)

Supporting Evidence and Relevance:

In the study entitled "(b) (4))", the Study Protocol states that the study is to be performed in compliance with 21 CFR Part 58. However, the study

contains analyses not performed according to GLPs; use of non-GLP contractors is also documented in the protocol as well as in study correspondences obtained during the inspection.

GLP Statement:
Exhibit 1, page 7
Use of Non-GLP contractors:
Exhibit 1, pages 5, 8, 20
Exhibits 43, 44, 45

Discussion with Management:

It was explained to firm representatives that studies being conducted at this site are required to be in compliance with FDA GLP regulations. Firm representatives were cooperative, did not commit to the initiation/implementation of corrective actions and stated that a written response would be submitted to NYK-DO DD.

OBSERVATION 3

The quality assurance unit did not monitor each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls were in conformance with FDA GLP regulations.

Specifically, protocols for the following studies state that these studies are to be performed in compliance with 21 CFR Part 58. However, both studies contain analyses not performed according to GLPs including serum analyses for all vaccine titers, water analyses, blood and fecal analyses, gross necropsy, histopathology evaluations, slit lamp and indirect opthalmoscopy examinations and the manufacture and analysis of the test material. The firm's QAU does not monitor contractors utilized in the generation of study data.

(b) (4)

Reference: 21 CFR 58.35(a)

Supporting Evidence:

The firm could not explain why some contracted services were not compliant with the GLP regulations other than to state that the sponsor had requested the use of the non-GLP testing facilities. The firm's QAU does not monitor contractors utilized in the generation of study data or examine procedures used by the contractor to determine that such procedures are GLP compliant. No documentation of contractor monitoring was available at the firm during our inspection.

Discussion with Management:

It was explained to firm representatives that studies being conducted at this site and contractors utilized in the generation of study data are required to be in compliance with FDA GLP regulations. Firm representatives were cooperative, did not commit to the initiation/implementation of corrective actions and stated that a written response would be submitted to NYK-DO DD.

OBSERVATION 4

Not all consulting laboratories, contractors, or grantees were notified that the study must be conducted in compliance with FDA GLP regulations.

Specifically, protocols for the following studies state that these studies are to be performed in compliance with 21 CFR Part 58. The firm failed to notify all contractors utilized for data generation in their GLP studies that their services must comply with GLP regulations.

(b) (4)

Reference: 21 CFR 58.10

Supporting Evidence and Relevance:

The firm does not notify contractors that the study/generation of study data must be conducted in compliance with FDA GLP regulations. The firm could not explain why some contracted services were not compliant with the GLP regulations other than to state that the sponsor had requested the use of the non-GLP testing facilities. No documentation of contractor notification was available at the firm during our inspection. Although there is some SOP guidance on project initiation (**Exhibit 29**), firm representatives stated that the signed protocol is considered by LRI to represent contractual responsibilities/acceptance between LRI and any sponsor.

Discussion with Management:

It was explained to firm representatives that studies being conducted at this site and contractors utilized in the generation of study data are required to be in compliance with FDA GLP regulations. Firm representatives were cooperative, did not commit to the initiation/implementation of corrective actions and stated that a written response would be submitted to NYK-DO DD.

OBSERVATION 5

The study director failed to assure that all experimental data, including observations of unanticipated responses of the test system, were accurately recorded and verified.

Specifically, in conjunction with the study "(b) (4))", the study director failed to assure that all study data were accurately recorded and verified according to firm SOP for data collection for "data that will be considered necessary to fully document research studies", and evidenced by the following SOP and protocol deviations noted in this study:

- Due to "technical error", detailed clinical observations were not conducted on Study day 56 for all animals.
- The temperature log book for samples collected on study day 27 could not be located.
- On October 23, 2008, the observing technician did not record their initial and the date.
- On November 2, 2008, the technician that recorded the time dosed, did not record their initials.
- On November 3, 2008, the recording technician did not record their initials.

Reference: 21 CFR 58.33(b)

Supporting Evidence: SOP and protocol deviations, **Exhibits 46, 47, 48**

Discussion with Management:

Firm representatives were cooperative, did not commit to the initiation/implementation of corrective actions and stated that a written response would be submitted to NYK-DO DD.

OBSERVATION 6

The testing facility does not have written standard operating procedures setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study.

Specifically, the firm does not have written standard operating procedures for, including but not limited to, the following:

- Criteria for the determination of degree of severity of protocol and/or SOP deviations
- Mitigation of study bias
- Certification of Copies
- Transfer of Study Data
- Utilization of Contractors
- Sponsor Responsibilities
- Protocol training
- QAU Evaluation of Contractors per GLPs

Reference: 21 CFR 58.81(a)

Supporting Evidence:

Exhibit 26; the firm's SOP Index fails to indicate written procedures for the areas listed above.

Discussion with Management:

Firm representatives were cooperative, did not commit to the initiation/implementation of corrective actions and stated that a written response would be submitted to NYK-DO DD.

OBSERVATION 7

Not all nonclinical laboratory studies were conducted in accordance with the protocol.

Specifically, in the folllowing studies, the protcols state that the raw data, original signed protocol and all other study documentation will be transferred to the sponsors for archiving and that the testing facilty will retain true, accurate, certified and/or exact copies of the raw data, protocols and study reports. The firm has no verification of and/or procedures in place to ensure accurate, certified and/or exact copies of study data as specified in the protocols.

(b) (4)

Reference: 21 CFR 58.130(a)

Supporting Evidence: Raw data disposition statements, **Exhibit 2, page 27 and Exhibit 3, page 13**

Discussion with Management:

Firm representatives were cooperative, did not commit to the initiation/implementation of corrective actions and stated that a written response would be submitted to NYK-DO DD.

OBSERVATION 8

Not all individuals engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have education, training, and experience, or combination thereof, to enable that individual to perform assigned functions.

Specifically, in the study "(b) (4))", SOP deviations were noted involving required training and data collection, for which training/re-training was listed as the corrective action; no documentation of the corrective

actions/trainings was noted in corresponding study employee files.

Reference: 21 CFR 58.29(a)

Supporting Evidence: Sop Deviations, **Exhibits 49 and 50**

Discussion with Management:

Firm representatives were cooperative, did not commit to the initiation/implementation of corrective actions and stated that a written response would be submitted to NYK-DO DD.

OBSERVATION 9

Testing facility management failed to assure that all test and control articles or mixtures had been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

Specifically, the firm failed to assure, through contributing scientist's reports and data to support the COA, that the sponsor had characterized the test article, determined the stability of the test article and its mixtures and determined the homogeneity and concentration of test article mixtures per GLP regulations for the following studies:

(b) (4)

Reference: 21 CFR 58.31(d)

Supporting Evidence and Relevance:

Though the firm states that test article stability under conditions of use is determined by the sponsor, the firm failed to assure, through contributing scientist's reports/data to support the CoA, that the sponsor had determined the stability of the test article and its mixtures per GLP under experimental conditions. The firm only maintains copies of the CoA and/or MSDSs provided by the sponsor upon receipt of the test article.

Exhibits 51 and 52 are indicative of the information received by the firm on the test article(s).

Exhibit 53 is a sponsor response to this observation, generated during our inspection, as it pertains to the test article utilized in the study entitled "(b) (4)

Discussion with Management:

Firm representatives were cooperative, did not commit to the initiation/implementation of corrective actions and stated that a written response would be submitted to NYK-DO DD.

OBSERVATION 10

Archives failed to provide for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports.

Specifically, due to recent relocation of the firm's archives and the re-organization of archiving staff, the retrieval of raw data, documentation, protocols and final reports requested during inspection was difficult and time consuming for firm representatives and resulted in the inability of the firm to produce temperature data logs for the study "(b) (4)

Reference: 21 CFR 58.190(b)

Supporting Evidence and Relevance:

During our inspection, the 2008 temperature monitoring log for the Talmadge Hill site, specifically relating to the study entitled "The (b) (4) ", could not be located.

Discussion with Management:

Exhibit 54 is the firm's Deviation Report generated during our inspection in response to this situation.

REFUSALS

No refusals were encountered during this inspection.

DISCUSSION WITH MANAGEMENT

On the final date of the inspection, during closeout and my issuance of the Inspectional Observations (FDA 483) to Michael J. Garrison, General Manager, in the physical absence of William M. Waring, President and CEO, the following individuals were present as indicated:

Beth Bell	Director of Research	Present at 17C site
(b) (6) (b) (6)	Sr. Study Coordinator/Research Marketing Associate	Present at 17C site
George Rucci	Sr. Study Coordinator	Present via telephone conference from Talmadge Hill South site
Michael J. Garrison	General Manager	Present at 17C site
Tanya L. Shaffer	Study Coordinator and Interim Facility Manager	Present via telephone conference from Talmadge Hill South site
Tina L. Yanchis-Kirby	Quality Assurance Director	Present at 17C site
William M. Waring	President and CEO	Present via telephone conference from North Carolina

The Inspectional Observations (FDA 483) was discussed. Firm representatives were cooperative but did not commit to the initiation/implementation of corrective actions.

The firm's management was informed by me that they have the opportunity to respond to the FDA 483 observations, and observations discussed with management, in writing, within 15 business days to the district office/District Director and that their response will be considered by the Agency before determining action. Representatives present stated that a written response would be submitted to NYK-DO DD- I provided the appropriate information.

I discussed the following items, noted during my inspection, with firm representatives and I stated that, although these items were not included on the FDA 483, in my opinion, these issues should merit voluntary firm consideration and/or resolution:

- In our review of protocol/sop deviations at the firm, we noted that explanations for a number of the deviations were listed as "technical oversight" and/or "technical error" with the resulting deviation effect of "This deviation will not affect the validity or integrity of data collected". We did not note written definitions/parameters for these three classifications.
- We noted, during our inspection, that key employees appear to be performing a number of duties. For example:
  - Tina L. Yanchis-Kirby, in addition to her primary role as the sole member of the Quality Assurance Unit, is also responsible for the firm archives and employee training.
  - Tanya L. Shaffer, in addition to her primary role as a Study Coordinator, is also currently serving as Interim Facility Manager at the Talmadge Hill South site.
- We noted, during our inspection, that key employees have not had non-firm affiliated GLP training since at least 2008. Tina L. Yanchis-Kirby, Quality Assurance Director, performs all GLP training for LRI employees. Taking into account the knowledge required to perform GLP training and attendance at her own trainings, Ms. Kirby has not "received" GLP training

since at least 2008 when she attended a professional development seminar, which included a GLP segment, presented by the Society of Quality Assurance.

- Review of the firm's SOPs revealed that the firm has failed to follow their written SOPs as follows:
  - ❖ As per Observation 10, the failure of the firm to follow their SOP for Raw Data Notebooks
  - ❖ Per the firm's SOP for SOPs (**Exhibit 27**), and documented on the SOP index (**Exhibit 26**), it appears that SOP review has not been completed "every (b) (4) or as needed".
  - ❖ Though not FDA GLP related, the firm is failing to meet all Annual training requirements as listed in their training SOP (**Exhibit 31**).

  I stressed the need for the firm to continually review and re-evaluate their SOPs in order to maintain procedural accuracy in a manner consistent with what the firm is actually and currently performing.
- During our review of IACUC meeting minutes/associated in-house inspections (**Exhibits 16-22**), we noted consistent, on-going issues with expired drugs, collection supplies/blood tubes, catheters, solutions….. Though we did not note any expiration issues during our study data reviews, we felt the issue presented concern/potential crossover into study realms and might require more attention.
- We determined that the firm did not require/request sponsor-monitor audit reports. We stressed that it was the firm's responsibility to make sure that these reports are available.
- We noted, in study data dating back to 2005, that technicians utilized "down arrows" in data columns. The use of these and/or "ditto" marks instead of specific information, initials, or signatures is not fully informative, are not sufficiently descriptive where actual values are needed and cannot be directly related to the recorder. Ms. Yanchis-Kirby stated that she had been working with employees to eliminate this practice.
- In the study entitled "(b) (4))", the sponsor's monitor is included on the LRI Personnel Signature Sheet and, as such, appears that the sponsor's monitor is personnel of LRI. We determined that the monitor is not affiliated with LRI and that his signature was included as a means of identification since the monitor was required to sign in/out on various logs while on the premises. We suggested developing an alternate signature form/method for non-LRI affiliated study personnel to avoid this same confusion.

At the conclusion of the inspection, I discussed with firm representatives the function of the FDA as a regulatory agency, the firm's requirements and responsibilities under the FD&C Act and FDA actions/penalties that can be associated with noncompliance, specifically, at firm request, FDA Warning Letters.

FDA 483 AMENDMENT

During the process of generating this Establishment Inspection Report (EIR), it came to my attention that I had documented the incorrect study as it relates to Observation 10 on the FDA 483. As issued on 3.1.11 (**Attachment 3**), Observation 10, page 5 of the FDA 483 reads:

"Specifically, due to recent relocation of the firm's archives and the re-organization of archiving staff, the retrieval of raw data, documentation, protocols and final reports requested during inspection was difficult and time consuming for firm representatives and resulted in the inability of the firm to produce temperature data logs for the study "(b) (4))" ."

I amended the original FDA 483, on 3.14.11, to read verbatim as follows:

"Specifically, due to recent relocation of the firm's archives and the re-organization of archiving staff, the retrieval of raw data, documentation, protocols and final reports requested during inspection was difficult and time consuming for firm representatives and resulted in the inability of the firm to produce temperature data logs for the study "(b) (4))" "(b) (4)

I supplied the original signed amended FDA 483 with correspondence, via UPS, to Michael J. Garrison, General Manager, for the firm's records. I also contacted Mr. Garrison via telephone to discuss the change. I retained a copy of the document for inclusion with this EIR (**Attachment 5**) and have duly noted the amendment within this report. UPS Delivery verification of the amended FDA 483 is included as **Attachment 6**.

ATTACHMENTS

1 Notice of Inspection (FDA 482), dated 2.15.11, issued to Michael J. Garrison, General Manager, 1 page

2 Notice of Inspection (FDA 482), dated 2.18.11, issued to Tanya L. Shaffer, Study Coordinator and Interim Facility Manager Talmadge Hill South, 1 page

3 Inspectional Observations (FDA 483) issued to Michael J. Garrison, General Manager on 3.1.11, 5 pages

4 Center/NYK-DO correspondences in conjunction with assignment/inspectional intent/depth and special instructions, 24 pages

5 Amended copy of original FDA 483 and correspondence, generated on 3.14.11, 8 pages

6 UPS Delivery verification of the amended FDA 483, 1 page

EXHIBITS

1 Protocol for Study: (b) (4) 74 pages

2 Protocol for Study: (b) (4)), 30 pages

3 Protocol for Study: (b) (4) 41 pages

4 Current LRI organizational charts, 3 pages

5 Job Description LRI Sr. Study Coordinator/Research Marketing Associate, 2 pages

6 Job Description LRI Quality Assurance Director, 2 pages

7 Job Description LRI Study Coordinator, 2 pages

8 Master Schedule as of January 2011, 1 page

9 Master Schedule as of December 2010, 4 pages

10 Master Schedule as of December 2009, 2 pages

11 Master Schedule as of December 2005, 1 page

12 Facility Licenses and Certifications, 8 pages

13 List of Sub-contractors used by LRI, 2 pages

14 LRI IACUC Members, 1 page

15 LRI IACUC SOP FAC.1100.002, 5 pages

16 LRI IACUC Meeting Minutes for August 26, 2010, 1 page

17 LRI IACUC Meeting Minutes for February 16, 2010, 1 page

18 LRI IACUC Meeting Minutes for September 29, 2009, 1 page

19 LRI IACUC Meeting Minutes for July 29, 2009, 1 page

20 LRI IACUC Meeting Minutes for February 9, 2009, 1 page

21 LRI IACUC Meeting Minutes for June 25, 2008, 25 pages

22 LRI IACUC Meeting Minutes for March, August, September, October and November, 2008, 6 pages

23 LRI IACUC Review & Approval for LRI Study No: 07.0446.072, 5 pages

24 LRI IACUC Review & Approval for LRI Study No: 04.2520.023, 2 pages

25 LRI IACUC Review & Approval for LRI Study No: 08.2520.031, 4 pages

26 LRI SOP Index, 5 pages

27 LRI SOP Facility Management Standard Operating Procedures FAC 1100.001, 4 pages

28 LRI SOP Responsibilities of the Quality Assurance Unit QAU.2900.001, 2 pages

29 LRI SOP Project Initiation PRJ.2200.001, 1 page

30 LRI SOP Sponsor's Protocol PRJ.2200.003, 2 pages

31 LRI SOP Training FAC.1100.003, 3 pages

32 LRI SOP Study Data Collection DAT.2700.002, 2 pages

33 LRI SOP Accounting and Data Records TCA.2300.002, 1 page

34 LRI SOP Inspections QAU.2900.002, 4 pages

35 LRI SOP Record Keeping QAU.2900.003, 4 pages

36 LRI SOP Auditing Study Data and Reports QAU.2900.005, 2 pages

37 LRI SOP Data Collection and Record Keeping COL.3100.006, 4 pages

38 LRI SOP Archives ARC.1300.001, 2 pages

39 LRI SOP Assignment of Project Numbers PRJ.2200.002, 1 page

40 LRI SOP Documenting Protocol Deviations PRJ.2200.007, 1 page

41 LRI SOP Test Article Handling TCA.2300.001, 3 pages

42 Firm site Diagrams, 2 pages

43 Non-GLP contractors study correspondence for study entitled "(b) (4) 1 page

44 Non-GLP contractors study correspondence for study entitled "(b) (4) ", 1 page

45 Non-GLP contractors study correspondence for study entitled "(b) (4) , 1 page

46 Protocol deviation No. 13 in conjunction with the study entitled "(b) (4) ", 1 page

47 Protocol deviation No. 14 in conjunction with the study entitled "(b) (4) ", 1 page

48 SOP deviation No. 10-009 in conjunction with the study entitled "(b) (4))", 1 page

49 SOP deviation No. 08-020 for study "(b) (4) ", 1 page

50 SOP deviation No. 09-013 for study "(b) (4) ", 1 page

51 Test Article CoA, 1 page

52 Test Article CoA and MSDS, 9 pages

53 Sponsor response pertaining to the test article utilized in the study entitled "(b) (4) ", 3 pages

54 SOP deviation No. 11-003, 1 page

55 Key to the Master Schedule sponsor ID coding, 1 page

56 Job Description President and CEO, 2 pages

57 Job Description General Manager, 2 pages

58 Job Description Director of Research, 1 page

59 LRI IACUC Meeting Minutes for June 28, 2010, 19 pages

60 LRI IACUC Meeting Minutes for December 10, 2009, 16 pages

61 LRI IACUC Meeting Minutes for December 16, 2008, 23 pages

Kathryn A. Nagy, Investigator

Joanne M. Schlossin, Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	02/15/2011 - 03/01/2011* FEI NUMBER 1311921

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Michael J. Garrison, General Manager

FIRM NAME	STREET ADDRESS
Liberty Research Inc.	170 Route 17c PO Box 107
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Waverly, NY 14892-0107	Nonclinical Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Testing facility management failed to assure that all personnel clearly understood the functions they were to perform.

Specifically,

A. Protocols for the following studies state that these studies are to be performed in compliance with 21 CFR Part 58. However, both studies contain analyses not performed according to GLPs including serum analyses for all vaccine titers, water analyses, blood and fecal analyses, gross necropsy, histopathology evaluations, slit lamp and indirect opthalmoscopy examinations and the manufacture and analysis of the test material.
   - (b) (4)
   - (b) (4)

B. The firm's QAU does not monitor contractors utilized in the generation of study data.
C. The firm failed to notify all contractors utilized for data generation in their GLP studies that their services must comply with GLP regulations.
D. The study director failed to assure that all experimental data, including observations of unanticipated responses of the test system, were accurately recorded and verified.
E. The testing facility does not have adequate written standard operating procedures setting forth nonclinical laboratory study methods that are adequate to insure the quality and integrity of the data generated in the course of a study.

OBSERVATION 2

The study director failed to assure that all applicable GLP regulations were followed.

Specifically, protocols for the following studies state that these studies are to be performed in compliance with 21 CFR Part 58. However, both studies contain analyses not performed according to GLPs including serum analyses for all vaccine titers,

AMENDMENT 1

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	Kathryn A. Nagy, Investigator Joanne M. Schlossin, Investigator	03/14/2011

water analyses, blood and fecal analyses, gross necropsy, histopathology evaluations, slit lamp and indirect opthalmoscopy examinations and the manufacture and analysis of the test material. The study director for these studies, failed to assure that all applicable GLP regulations were followed as they apply to the contractors utilized in the generation of study data.

- (b) (4)
- (b) (4)

OBSERVATION 3

The quality assurance unit did not monitor each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls were in conformance with FDA GLP regulations.

Specifically, protocols for the following studies state that these studies are to be performed in compliance with 21 CFR Part 58. However, both studies contain analyses not performed according to GLPs including serum analyses for all vaccine titers, water analyses, blood and fecal analyses, gross necropsy, histopathology evaluations, slit lamp and indirect opthalmoscopy examinations and the manufacture and analysis of the test material. The firm's QAU does not monitor contractors utilized in the generation of study data.

- (b) (4)
- (b) (4)

OBSERVATION 4

Not all consulting laboratories, contractors, or grantees were notified that the study must be conducted in compliance with FDA GLP regulations.

Specifically, protocols for the following studies state that these studies are to be performed in compliance with 21 CFR Part 58. The firm failed to notify all contractors utilized for data generation in their GLP studies that their services must comply with GLP regulations.

- (b) (4)

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- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)

OBSERVATION 5

The study director failed to assure that all experimental data, including observations of unanticipated responses of the test system, were accurately recorded and verified.

Specifically, in conjunction with the study '(b) (4))", the study director failed to assure that all study data were accurately recorded and verified according to firm SOP for data collection for "data that will be considered necessary to fully document research studies", and evidenced by the following SOP and protocol deviations noted in this study:

- Due to "technical error", detailed clinical observations were not conducted on Study day 56 for all animals.
- The temperature log book for samples collected on study day 27 could not be located.
- On October 23, 2008, the observing technician did not record their initial and the date.
- On November 2, 2008, the technician that recorded the time dosed, did not record their initials.
- On November 3, 2008, the recording technician did not record their initials.

OBSERVATION 6

The testing facility does not have written standard operating procedures setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study.

Specifically, the firm does not have written standard operating procedures for, including but not limited to, the following:

- Criteria for the determination of degree of severity of protocol and/or SOP deviations
- Mitigation of study bias
- Certification of Copies
- Transfer of Study Data

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- Utilization of Contractors
- Sponsor Responsibilities
- Protocol training
- QAU Evaluation of Contractors per GLPs

OBSERVATION 7

Not all nonclinical laboratory studies were conducted in accordance with the protocol.

Specifically, in the folllowing studies, the protcols state that the raw data, original signed protocol and all other study documentation will be transferred to the sponsors for archiving and that the testing facilty will retain true, accurate, certified and/or exact copies of the raw data, protocols and study reports. The firm has no verification of and/or procedures in place to ensure accurate, certified and/or exact copies of study data as specified in the protocols.

- (b) (4)
- (b) (4)

OBSERVATION 8

Not all individuals engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have education, training, and experience, or combination thereof, to enable that individual to perform assigned functions.

Specifically, in the study '(b) (4) ", SOP deviations were noted involving required training and data collection, for which training/re-training was listed as the corrective action; no documentation of the corrective actions/trainings was noted in corresponding study employee files.

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OBSERVATION 9

Testing facility management failed to assure that all test and control articles or mixtures had been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

Specifically, the firm failed to assure, through contributing scientist's reports and data to support the COA, that the sponsor had characterized the test article, determined the stability of the test article and its mixtures and determined the homogeneity and concentration of test article mixtures per GLP regulations for the following studies:

- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)

OBSERVATION 10

Archives failed to provide for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports.

Specifically, due to recent relocation of the firm's archives and the re-organization of archiving staff, the retrieval of raw data, documentation, protocols and final reports requested during inspection was difficult and time consuming for firm representatives and resulted in the inability of the firm to produce temperature data logs for the study (b) (4) ".

*** DATES OF INSPECTION:**
02/15/2011(Tue), 02/16/2011(Wed), 02/17/2011(Thu), 02/18/2011(Fri), 02/21/2011(Mon), 02/22/2011(Tue), 02/23/2011(Wed), 03/01/2011(Tue)

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