



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: **36525**

800 UNIVERSITY AVENUE

Certificate: **93-R-0506**

Site: 001

T. B. HOLDINGS, L.L.C.

BERKELEY, CA 94710

Type: ROUTINE INSPECTION

Date: Nov-30-2008

No non compliant items identified during this inspection.

This is a transcribed copy of the original inspection report

Prepared By:

MICHAEL J SMITH, V.M.O. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5019

Mar-26-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Mar-26-2009



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: **36525**

800 UNIVERSITY AVENUE

Certificate: **93-R-0506**

Site: 001

T. B. HOLDINGS, L.L.C.

BERKELEY, CA 94710

Type: ROUTINE INSPECTION

Date: Oct-02-2007

No non compliances identified during this inspection.

Prepared By:

MICHAEL J SMITH, V.M.O. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5019

Oct-02-2007

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Oct-02-2007



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: **36525**

Certificate: **93-R-0506**

Site: 002

T. B. HOLDINGS, L.L.C.

800 UNIVERSITY AVENUE

Type: ROUTINE INSPECTION

BERKELEY, CA 94710

Date: May-27-2010

No non-compliant items identified during this inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Jun-02-2010

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jun-02-2010



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: **36525**

Certificate: **93-R-0506**

Site: 002

800 UNIVERSITY AVENUE

T. B. HOLDINGS, L.L.C.

Type: ROUTINE INSPECTION

Date: Nov-30-2009

BERKELEY, CA 94710

No animals regulated by the Animal Welfare Act were present at the time of the inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Dec-10-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Dec-10-2009



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: **36525**

Certificate: **93-R-0506**

Site: 002

800 UNIVERSITY AVENUE

T. B. HOLDINGS, L.L.C.

Type: ROUTINE INSPECTION

Date: Sep-29-2009

BERKELEY, CA 94710

No animals regulated by the Animal Welfare Act were present at the time of the inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Oct-02-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Oct-02-2009



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: **36525**

Certificate: **93-R-0506**

Site: 002

T. B. HOLDINGS, L.L.C.

800 UNIVERSITY AVENUE

Type: ROUTINE INSPECTION

BERKELEY, CA 94710

Date: Jun-11-2009

No animals regulated by the Animal Welfare Act were present at the time of the inspection, thus no noncompliant items were identified during this inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Jun-12-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jun-12-2009



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: **36525**

Certificate: **93-R-0506**

Site: 002

T. B. HOLDINGS, L.L.C.

800 UNIVERSITY AVENUE

Type: ROUTINE INSPECTION

BERKELEY, CA 94710

Date: Jun-12-2008

No animals regulated by the Animal Welfare Act were present at the time of the inspection, thus no noncompliant items were identified during this inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Jun-16-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jun-16-2008



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: **36525**

Certificate: **93-R-0506**

Site: 002

T. B. HOLDINGS, L.L.C.

800 UNIVERSITY AVENUE

Type: ROUTINE INSPECTION

BERKELEY, CA 94710

Date: Jul-23-2007

No noncompliant items were identified during this inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Jul-26-2007

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jul-27-2007



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: 36525

Certificate: 93-R-0506

Site: 003

800 UNIVERSITY AVENUE

T. B. HOLDINGS, L.L.C.

Type: ROUTINE INSPECTION

Date: Jul-28-2009

BERKELEY, CA 94710

2.31 (c) (7) **REPEAT**
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC)

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

Deviation # 1 to protocol 1327 (Evaluation of a restrictive device placed in the proximal stomach in a canine model using a two stage procedure) described the addition of an entirely different surgical procedure to the protocol without IACUC approval. The deviation form stated: "The creation of Roux-en Y and other bypass techniques allows for evaluation in a comparative fashion to the devices on study." Four animals received gastric bypass procedures without review and approval by the IACUC. The deviation also stated that four specific animals were initially chosen to receive the bypass procedures and one animal (ID# CYRICU) was mistakenly used instead of another animal (ID# CXXIBJ). Page 3 of the IACUC approved protocol 1327 states that: "The most effective, although risky, method of significant and lasting weight reduction in obese people is through a stomach reduction and bypass procedure ("Roux-en-Y"). This procedure has a significant amount of risk. It can lead to infection, complications, serious adverse events and even death." Except for the deviation, the addition of bypass procedures was not included in any amendments approved by the IACUC. The deviation form dated 7-3-08 stated that a draft addendum was signed on 4-5-08 but not routed through the IACUC for further review. The numbered and dated amendments to the protocol did not contain an amendment pertaining to adding the bypass surgery, thus it appears that the IACUC never approved the use of the bypass procedures. The fact that there is no description of the procedures or justification for the number of animals used is addressed under the appropriate sections of this report.

The IACUC should review proposed significant changes to activities involving animals prior to the implementation of the activity. After reviewing the activities, the IACUC may approve the changes, require modifications to the activities, or withhold their approval. A system should be in place which would ensure that proposed significant changes to activities involving the care and use of animals are reviewed and approved by the IACUC prior to their implementation.

Previous correction date: October 30, 2008.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Aug-04-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-08-2009



Inspection Report

2.31 (e) (2) **REPEAT**

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC).

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

Two IACUC approved protocols contained inadequate rationales for the appropriateness of the number of animals to be used in the studies. Protocols 1327 and 1505 did not include an adequate justification for the number of animals to be used for those activities.

Protocol 1327 was cited on the previous inspection report of July 30, 2008 for an inadequate justification for the number of animals to be used in the study with a correction date of October 30, 2008. At the time of this inspection there had been no amendments to the protocol addressing the number of animals being used since the previous inspection. Thus the protocol had not been corrected since the previous inspection. Protocol 1327 was approved for 100 animals, divided into two groups of 25 (acute use) and 75 (chronic use). However the rationale provided in the protocol did not explain how those numbers were derived. Also, four animals were used in an additional, unapproved, procedure with no rationale as to why four animals were needed.

Protocol 1505 also did not provide an adequate justification for the number of animals being used in the study. Ten animals were approved for use in this study. The justification included a reference to one "test animal" plus 10 percutaneous test devices and six subcutaneous test articles to be implanted during the study. There was no description of why 10 animals were needed for the study.

An adequate rationale for the appropriateness of the number of animals to be used is important in order to ensure that excessive numbers of animals are not used unnecessarily in that activity. Even underestimating the number of animals needed for a study may ultimately lead to excessive animal use. If an inadequate number of animals were used initially, the activity may need to be duplicated with additional animals in order to obtain the required information. An adequate rationale for the appropriateness of the number of animals must be included in each protocol in order that the IACUC may review the activity and make decisions regarding approval of the activity.

Previous correction date: October 30, 2008.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Aug-04-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-08-2009



Inspection Report

2.31 (e) (3) **REPEAT**

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC).

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (3) A complete description of the proposed use of the animals.

IACUC approved protocols 1327 and 1505 did not contain a complete description of the proposed use of the animals.

Protocol 1327 did not completely describe the surgical approach for device placement. The description only stated that the abdomen would be opened using a standard approach. The protocol did not describe how the abdomen was to be entered or the length of the incision to be made. Additionally, the protocol only contained a brief description of the first procedure entitled "First surgical procedure" with no description of the IACUC approved second surgical procedure. Also, four dogs received surgical procedures documented in "Deviation #: 1" that was not included in the original protocol or in an amendment approved by the IACUC. There was no description of the bypass procedures in any of the documents provided at the time of the inspection.

Protocol 1505 provided almost no description of the procedures to be performed. The section of the protocol devoted to numbers of animals described potentially 10 different devices and six "test articles" but the protocol only provided a brief description for the implantation of one of these devices. For the remainder of the devices and articles the description is consists of: "the devices and test materials will be implanted in the dorsal area using a combination of skin incisions and percutaneous puncture." The protocol contained diagrams of four devices, but there is otherwise no description of what is to be implanted in the animal for the IACUC to consider. Additionally, the protocol provides for load testing and bacterial inoculation four weeks after the initial device implantation but does not describe how to proceed in case of adverse events such as infection prior to inoculation or device failure. Animal 3403 developed an infection at an implant site. Antibiotics were discontinued just prior to the four week post operative time point and the animal was then inoculated with bacteria.

The IACUC is responsible for reviewing all aspects of animal care and use, and evaluating protocols in order to ensure compliance with the Animal Welfare Act. In order to properly accomplish this function, the IACUC must be made aware of all procedures being conducted. It is the responsibility of the IACUC to ensure that the investigator provides a complete description of proposed activities that involve the use of animals in order that those activities may be adequately reviewed and determined to be in accordance with the Animal Welfare Act.

Previous correction date: October 30, 2008.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Aug-04-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-08-2009



Inspection Report

3.8

EXERCISE FOR DOGS.

Sec. 3.8 Exercise for dogs.

Dealers, exhibitors, and research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition, the plan must be approved by the attending veterinarian. The plan must include written standard procedures to be followed in providing the opportunity for exercise.

There was no specific exercise plan for dogs approved by the attending veterinarian in place at the time of the inspection. An SOP entitled "Care and Maintenance of Dogs" included three sentences referring to exercise that only specified that dogs in cages were allowed to run in a specific area daily. An additional statement that dogs housed in runs did not require additional space for exercise did not address individual verses group housing or adequate square footage and was thus inadequate.

The facility must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. The plan must be approved by the attending veterinarian.

This non-compliant item was corrected at the time of the inspection.

3.53 (c) (2)

PRIMARY ENCLOSURES.

Sec. 3.53 Primary enclosures.

All primary enclosures for rabbits shall conform to the following requirements:

(c) Space requirements for primary enclosures acquired on or after August 15, 1990.

(2) Each rabbit housed in a primary enclosure shall be provided a minimum amount of floor space, exclusive of the space taken up by food and water receptacles.

Most of the rabbits at the facility were being kept in enclosures that did not provide a sufficient amount of floor space. At the time of the inspection, all rabbits were being kept in enclosures that provided 3.5 square feet of floor space. Of the 28 rabbits at the facility, 24 rabbits weighed between 4.0 and 5.4 kilograms, thus requiring a minimum of 4 square feet of floor space. Additionally, three of the rabbits weighed in excess of 5.4 kilograms, thus requiring a minimum of 5 square feet of floor space.

Housing is an important aspect of animal husbandry and plays a significant role in animal health and well-being. Enclosures with insufficient space may have a negative impact on the animals being maintained there. A sufficient amount of floor space for rabbits is necessary in order to ensure that the animals have enough space to make normal postural adjustments and adequate freedom of movement. The facility should ensure that the cages housing their animals meet the required minimum floor space set forth in the regulations.

This non-compliant item was corrected at the time of the inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title:

VETERINARY MEDICAL OFFICER Inspector 5039

Aug-04-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-08-2009



Inspection Report

Note:

Accompanied by Dr. Steve Drlica.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Date:

Aug-04-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Sep-08-2009

Title:



Inspection Report

T. B. HOLDINGS, L.L.C.

Customer ID: **36525**

Certificate: **93-R-0506**

Site: 003

T. B. HOLDINGS, L.L.C.

800 UNIVERSITY AVENUE

Type: ROUTINE INSPECTION

BERKELEY, CA 94710

Date: Jul-30-2008

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC)

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

Amendment # 001 to IACUC approved protocol # ANS 1444 describes changes in the species and number of animals to be used for the procedure. These changes are considered to be significant changes to a protocol and thus should be reviewed and approved by the IACUC. However these changes were not reviewed and approved by the IACUC prior to the use of animals in the ongoing activity. According to a staff member, a veterinarian at the facility inappropriately signed off on the change on July 29, 2008 without the knowledge and approval of the IACUC. The activity was in progress on the first day of the inspection, July 30, 2008.

The IACUC should review proposed significant changes to activities involving animals prior to the implementation of the activity. Following the review of the activities, the IACUC may approve the changes or it may require modifications to the activities, or withhold their approval. A system should be in place which would ensure that proposed significant changes to activities involving the care and use of animals are reviewed and approved by the IACUC prior to their implementation.

Correct on all active and future protocols by October 30, 2008.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Aug-07-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-30-2008



Inspection Report

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC)

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

(2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

Two IACUC approved protocols contained inadequate rationales for the appropriateness of the number of animals to be used in the studies. One protocol (ANS 1327) was approved for 100 dogs, divided into two groups of 25 (acute use) and 75 (chronic use). However the rationale provided in the protocol did not adequately explain how the numbers were derived. The second protocol (ANS-1452, dated July 29, 2008) also contained an inadequate rationale for the appropriateness of the number of animals to be used for the study. The justification given in the original approved protocol was that six animals "will give a reasonable amount of data without using an excessive amount of animals." Amendment #1 (dated July 31, 2008) added two additional animals and one test article to the protocol, then split the eight animals into groups of four. No rationale was provided in the amendment to explain why eight animals were needed for the protocol and no rationale was provided to explain why six animals were thought to be needed to evaluate the first test article in the original protocol, but only four were needed to evaluate the same article when the amendment was approved.

An adequate rationale for the appropriateness of the number of animals to be used is important in order to ensure that excessive numbers of animals are not used unnecessarily in that activity. Even underestimating the number of animals needed for a study may ultimately lead to excessive animal use. If an inadequate number of animals were used initially, the activity may need to be duplicated with additional animals in order to obtain the required information. An adequate rationale for the appropriateness of the number of animals must be included in each protocol in order that the IACUC may review the activity and make decisions regarding approval of the activity.

Correct on all active and future protocols by October 30, 2008.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Aug-07-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-30-2008



Inspection Report

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(3) A complete description of the proposed use of the animals.

IACUC approved protocol ANS-1454 did not contain a complete description of the proposed use of the animals. There was no reference to surgery at all in the description, even though the procedure being performed was training for cardiac bypass surgery and included opening the thoracic cavity and exposing the heart. Additionally, there was an inadequate description of how the animal was to be prepared for the surgery. The protocol stated that "Animals will have surgical catheters and cannulas placed." Later in the protocol there is an additional statement regarding an arterial catheter being placed, also with no reference to the location of the catheter. It is unclear from the narrative if the first reference was independent of the second reference.

It is the responsibility of the IACUC to ensure that the investigator provides a complete description of proposed activities that involve the use of animals in order that those activities may be adequately reviewed and determined to be in accordance with the Animal Welfare Act.

Correct on all active and future protocols by October 30, 2008.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Aug-07-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-30-2008



Inspection Report

Note:

The inspection was performed in two parts, with the first date being July 30, 2008 and the second date being August 6, 2008.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Date:

Aug-07-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Sep-30-2008

Title: