



## Inspection Report

T. B. Holdings L L C  
1031 Bing Street  
San Carlos, CA 94070

Customer ID: **36525**  
Certificate: **93-R-0506**  
Site: 003  
T. B. HOLDINGS, L.L.C.

Type: ROUTINE INSPECTION  
Date: 27-AUG-2015

### 2.31(d)(1)(1)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Five IACUC (Institutional Animal Care and Use Committee) approved protocols do not contain assurances that procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.

Protocols 1853, 2129, 2133, and 2030 do not address potentially distressful or painful effects of the activities. Expected or possible adverse effects of the study are not described, nor are there are descriptions of how any adverse health effects are to be addressed by the staff.

Protocol 2099 contains an end point criteria statement, however only one of the three criteria address the animals and only states that the study will be terminated if the animal develops intractable complication such as sepsis or neurologic complications. Calf 1534 developed signs that were not consistent with sepsis or neurologic complications and the calf was not euthanized, but was allowed to die after the staff noted that the animal had become agonal. The protocol did not contain any reference to recognizing or treating signs of pain or discomfort.

Invasive procedures such as surgery and drug testing may cause discomfort, distress, and/or pain to animals. It is the responsibility of the IACUC to ensure that procedures involving animals avoid or minimize discomfort, distress, and pain to the animals. To perform this function the IACUC should ensure that protocols include discussions of the potential health effects of each activity and how those effects are to be addressed.

Correct by November 17, 2015 for the above protocols and new protocols from this time forward. Other current protocols with inadequate rationales for numbers should be corrected by November 17, 2016.

### 2.31(e)(2)

Prepared By: MARCY ROSENDALE, D V M USDA, APHIS, Animal Care

Date:  
05-JAN-2016

Title: VETERINARY MEDICAL OFFICER 5039

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### **INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

Four IACUC approved protocols do not provide adequate rationales for the number of animals to be used.

Protocols 2030, 2129, and 2099 state the number of animals to be used but do not provide rationales to explain the need for those numbers.

The IACUC is responsible for ensuring that appropriate numbers of animals are used in each approved activity. In order to perform this function the IACUC must know both how many animals are needed for an activity and why that number of animals is needed. It is the responsibility of the IACUC to ensure that each activity involving animals contains an adequate rationale for the number of animals being used.

Correct by November 17, 2015 for the above protocols and new protocols from this time forward. Other current protocols with inadequate rationales for numbers should be corrected by November 17, 2016.

### **2.31(e)(3)**

### **INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

Five IACUC approved protocols do not provide complete descriptions of the activities using animals.

Protocol 1853, a study using pigs, contains virtually no description of animal use.

Protocol 2129, a study using rabbits, contains no description of how or where aneurysms are created. The description of a subsequent treatment using an implanted device also contains no anatomical information. A reference to explanting the implants does not state whether the animals are to be alive or dead when the explant takes place.

Protocol 2133, a study using dogs, contains no description of where injections are to be given. Additionally, the protocol does not provide any assurances that excessive amounts of blood will not be collected, despite the fact that the dogs undergo serial blood collection and may be used in multiple studies.

Protocol 2099, a heart pump study using calves, contains an inadequate description of the surgical procedure and no description of the activities subsequent to the pump placement beyond stating that changes to the pump speed, lowering or eliminating anticoagulants, and/or constricting cannula outflow are to be performed.

Protocol 2030, a study using sheep, contains no description of where injections are to be given and contains an

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inadequate description of how the animals are to be used for multiple procedures.

It is the responsibility of the IACUC to ensure that animal activities are in compliance with the Animal Welfare Act. In order to perform this function, a complete description of activities using animals must be included in protocols prior to IACUC approval. The facility should ensure that all protocols contain complete descriptions of animal use.

Correct by November 17, 2015 for the above protocols and new protocols from this time forward. Other current protocols with inadequate rationales for numbers should be corrected by November 17, 2016.

### 2.33(b)(2) DIRECT

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Appropriate methods to prevent, control, diagnose, or treat diseases or injuries are not being used for some animals with health concerns.

Two dogs (CABCHZ and CACCGY) were each observed to have a round open lesion on a shaved area over their lower backs. The lesion on one dog was partially covered with a dark crusty material, consistent with scabbing. According to their veterinary care form, neither dog had been treated for the lesions prior to the inspection. The lesions were treated during the inspection, after inspectors brought the lesions to the attention of the staff. According to a veterinary staff member the lesions were caused by poor injection technique and the injections were study related.

One dog (CAHCZT) was observed to be sitting in its food bowl. The dog moved out of the bowl with difficulty and was observed to move gingerly in its enclosure and sit holding its back right foot extended and elevated off the stainless steel enclosure floor. Reddened skin was noted between some of the toes and a raised reddened lesion was noted on the right hind foot. The floor of the enclosure consisted of stainless steel bars and no bed was provided despite the foot lesions or the postural signs of discomfort. A large, raised, discolored skin lesion devoid of hair was observed on the lower jaw. Additionally dental issues were identified. An excessive amount of tartar was observed on several teeth and reddened and receding gums were observed on the upper right jaw. According to the veterinary care form the dog had not been treated for any of the above health issues.

One sheep (995) had overgrown back hooves.

The failure to use appropriate methods to prevent, control, diagnose, or treat diseases or injuries may cause pain and/or distress to the animals. The facility should insure that animals with diseases and injuries receive appropriate

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treatment.

Correct immediately.

### 2.33(b)(3) DIRECT

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Health conditions observed in three dogs (CABHZ, CACCGY, and CAHCZT) were not noted in their veterinary care forms and their conditions had not been conveyed to the attending veterinarian which resulted in the failure of the facility to provide treatment for the conditions. The veterinary care form for all three dogs noted only BAR (bright, alert, responsive) from 8/4/15 through the date of the inspection.

Failure to treat health conditions may lead to unnecessary pain and distress in animals. The facility should ensure that animals are appropriately monitored and health conditions are conveyed to the attending veterinarian in a timely manner.

Correct immediately.

### 2.33(b)(5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

A calf used in a cardiac study did not receive adequate post-procedural care in accordance with current established veterinary medical and nursing procedures.

A heart pump was implanted in calf 1534 on 6/30/2015. According to the veterinary care form, the calf appeared to be pacing and anxious at 5:04 p.m. the day of surgery at which time 550 cc of bloody fluid was suctioned from a chest tube. No other treatment was provided. At 6:00 the staff noted "Calf still agitated. Spinning and pacing..." which are all potential signs of pain. The calf was given a dose of acepromazine (a sedative) and a dose of an anticoagulant. Although the calf had undergone surgery the same day that involved cutting open the chest and showed signs consistent with being painful the calf was not treated for pain, but was instead given a sedative that would give no pain relief and would inhibit the expression of signs of pain.

The protocol for the study did not state that the animals should not be treated for pain and there was no scientific

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justification for withholding pain control from the animals being used in the protocol. Procedures that would reasonably be expected to cause more than slight or momentary pain or distress in human beings must be considered to be painful in animals. Surgeries that involve opening the chest cavity are known to cause more than slight or momentary pain in humans and thus must be considered to be painful in animals. Unless scientific justification is provided in the protocol to withhold treatment for pain animals should be treated for pain when appropriate to do so.

Correct immediately.

### 3.125(a)

#### FACILITIES, GENERAL.

Seven sheep were being housed in enclosures composed of differing types of fence panels that were connected by pieces of wire and bolts. Several sharp pieces of wire and long bolts were protruding into the enclosures. Sharp objects may injure the animals and the facility should ensure that enclosures are constructed in a manner that keeps the animals safe.

Correct by September 24, 2015.

### 3.131(a)

#### SANITATION.

Four calves were being housed in enclosures with excessive accumulations of feces and urine-soaked bedding. According to a staff member, the calf enclosures had not been cleaned as of 13:35 hours on the day of the inspection. The coat of one calf was soiled over the right hind leg and feces were noted in its otherwise empty plastic feeder. Most of the flooring surfaces were affected, thus the animals were unable to avoid exposure to their excrement.

Two sheep (955 and 995) were observed to have dirty wool over their hindquarters and abdomens that appeared to be dried excrement. Both sheep had been housed at the facility since 2014 and were being used in a study.

Excessive accumulations of excrement in animal enclosures may adversely affect animal health and wellbeing. Excreta should be removed from enclosures as often as necessary to prevent contamination of the animals and to minimize disease hazards and reduce odors.

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Correct immediately.

An exit briefing was conducted with a facility representative.

Accompanied by Dr. Pam Smith.

### Additional Inspectors

Smith Pamela, Veterinary Medical Officer

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## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
36525	93-R-0506	003	T. B. HOLDINGS, L.L.C.	27-AUG-15

Count	Scientific Name	Common Name
000004	<i>Bos taurus</i>	CATTLE / COW / OX / WATUSI
000047	<i>Canis lupus familiaris</i>	DOG ADULT
000003	<i>Capra hircus</i>	DOMESTIC GOAT
000016	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000017	<i>Ovis aries aries</i>	SHEEP INCLUDING ALL DOMESTIC BREEDS
000008	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
<b>000095</b>	<b>Total</b>	