



Inspection Report

SANTA CRUZ BIOTECHNOLOGY, INC.

Customer ID: **3832**

Certificate: **93-B-0192**

Site: 001

SANTA CRUZ BIOTECHNOLOGY, INC.

2145 DELAWARE AVENUE

Type: ROUTINE INSPECTION

SANTA CRUZ, CA 95060

Date: Feb-08-2011

2.40 (b) (2) REPEAT DIRECT NCI

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE (DEALERS AND EXHIBITORS).

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care.

Several instances of inappropriate methods to prevent, control, diagnose, and treat diseases and injuries were identified during the inspection.

The bandage on the left front foot of goat 6834 was dirty and worn. According to the medical record the bandage was last changed 28 days prior to the inspection.

Goat 14983 was found wedged in a metal feeder, unable to move its head out of the rungs of the feeder. Staff members removed the animal from the feeder and collapsed when placed on its feet, unable to stand or walk. The goat and feeder were outside in a lot with several other animals, with no protection from the elements. The ambulatory animals could move inside a building if they needed shade or shelter. This animal also had no protection from the other animals, which often stand in the feeders when eating. In addition to the inadequate husbandry, the animal was not receiving appropriate medical care for the condition cited in the medical record. The goat was last seen by the attending veterinarian the previous week. Since that date, staff members noted only a worsening of the condition, starting the day after their veterinarian examined the animal, yet the attending veterinarian was not consulted.

The facility is still failing to keep current weights on the animals. The weight of an animal is used to determine the maximum amount of blood that may be safely harvested and thus should be monitored on a routine basis when the animal is used for production. Body weight should also be monitored when animals are being treated for medical conditions.

This facility houses a large number of animals thus making accurate records essential to providing adequate veterinary care. The facility should take measures to ensure that medical issues are adequately documented by animal care and veterinary staff and that appropriate treatment is provided to animals with medical issues.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Feb-28-2011

Received By:

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

Date:

Title:

Apr-05-2011



Inspection Report

Previous correction date: Correct immediately.

2.40 (b) (3) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE (DEALERS AND EXHIBITORS).

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

Seventy six goats being used at the facility were segregated from the main herds at the time of the inspection for various medical reasons. Health records for eight of the 76 goats were examined and all eight of those were found to be incomplete as well as containing insufficient detail to ensure that accurate information was conveyed to the attending veterinarian. There were vague or no descriptions of conditions such as acute injuries, lameness, respiratory, urinary, or neurologic diseases of the animals. Goat 8603 was observed to be lame, however lameness was not noted on the medical record.

Daily observations of all animals to assess their well-being, appropriate documentation of those observations, and direct and frequent communication with the attending veterinarian regarding health issues are necessary to ensure that the animals at the facility receive timely and adequate veterinary care. A system should be in place to ensure that all animals are observed daily, any health problems are adequately documented, and the attending veterinarian is notified when necessary.

Previous correction date: Correct immediately.

Note:
An exit briefing was conducted with a facility representative.
Accompanied by Dr. Alexandra Andricos.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Feb-28-2011

Received By:

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

Date:

Title:

Apr-05-2011



Inspection Report

SANTA CRUZ BIOTECHNOLOGY, INC.

Customer ID: 1344

Certificate: 93-R-0380

Site: 002

SANTA CRUZ BIOTECHNOLOGY, INC.

2145 DELAWARE AVENUE

Type: ROUTINE INSPECTION

SANTA CRUZ, CA 95060

Date: Feb-08-2011

2.31 (c) (7)

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.

The IACUC approved protocol regarding plasmaphoresis in goats specified that plasma should be "collected at weekly or longer intervals." Goat 2375 underwent plasma collection on 5/21/2009 and again on 5/27/2009, one day less than the required minimum seven day time period.

Collecting plasma at shorter intervals than put forth in the protocol and approved by the IACUC could cause harm to the animals. 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 by April 15, 2011.

2.31 (d) (1) (i) **REPEAT**

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

(i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.

The IACUC approved protocol calls for whole blood collection in goats of "1 - 1.5 % of body weight..."

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Feb-28-2011

Received By:

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

Date:

Title:

Apr-05-2011



Inspection Report

citing two internet references in support of the figures. The first reference is a link to a Yale University page that is password protected and thus could not be checked. The second reference was a page from the University of Minnesota entitled "Guidelines for Collection of Blood from Experimental Animals." According to this site as referenced by the protocol: "For multiple blood draws separated by a period of weeks, a maximum of 1% of the animal's body weight can be removed, i.e., 0.15 ml from a 15 gram mouse; 50 ml from a 5 kg cat; 400 ml from a 40 kg dog. A 14 day recovery period is needed for the average healthy adult animal to recover from this blood loss." The words "...a maximum of 1% of the animal's body weight can be removed.." was in bold face at this site. Several other online guidelines from other major universities were reviewed and none recommended withdrawing more than the lower figure of one percent except as a terminal procedure. Additionally, this approved protocol adds that the amounts collected "...may vary by +/- 10%." As written in the protocol, goats might have volumes of blood collected in excess of the 1.5% figure and be expected to have additional blood collected in two weeks, prior to full recovery from the previous collection.

Whole blood collection records for six goats numbered 6834, 8603, 13310, 6140, 11005, and 6476 were obtained and examined. These animals were selected for record review because they were segregated from the main herds due to various, primarily chronic, health problems. Blood collected from five of these six goats exceeded one percent of their body weight for every collection over their life span. Blood collected from the sixth goat was above one percent of body weight 14 out of 19 times over its life span. Anemia was noted on the records of two of the goats, one of which had a hematocrit of 13 on the date of the inspection. A third goat had a decreasing hematocrit, while the records for the remaining three goats did not contain references to any hematocrit numbers.

Prior to approving a protocol, the IACUC should determine that procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals unless acceptable justification for the departure is provided in writing. As written, the protocol does not provide an acceptable justification for collecting blood in excess of what is traditionally considered safe, as stated in the supporting blood collection guideline.

Previous correction date: Correct immediately.

2.33 (b) (2) REPEAT DIRECT NCI ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

- (b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
- (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care.

Several instances of inappropriate methods to prevent, control, diagnose, and treat diseases and injuries were identified during the inspection.

The bandage on the left front foot of goat 6834 was dirty and worn. According to the medical record the bandage was last changed 28 days prior to the inspection.

Prepared By:

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

Date:

Feb-28-2011

Title:

VETERINARY MEDICAL OFFICER Inspector 5039

Received By:

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

Date:

Apr-05-2011

Title:



Inspection Report

Goat 14983 was found wedged in a metal feeder, unable to move its head out of the rungs of the feeder. Staff members removed the animal from the feeder and the goat collapsed when placed on its feet, unable to stand or walk. The goat and feeder were outside in a lot with several other animals, with no protection from the elements. The ambulatory animals could move inside a building if they needed shade or shelter. This animal also had no protection from the other animals, which often stand in the feeders when eating. In addition to the inadequate husbandry, the animal was not receiving appropriate medical care for the condition cited in the medical record. The goat was last seen by the attending veterinarian the previous week. Since that date, staff members noted only a worsening of the condition, starting the day after their veterinarian examined the animal, yet the attending veterinarian was not consulted.

The facility is still failing to keep current weights on the animals. The weight of an animal is used to determine the maximum amount of blood that may be safely harvested and thus should be monitored on a routine basis when the animal is used for production. Body weight should also be monitored when animals are being treated for medical conditions.

This facility houses a large number of animals thus making accurate records essential to providing adequate veterinary care. The facility should take measures to ensure that medical issues are adequately documented by animal care and veterinary staff and that appropriate treatment is provided to animals with medical issues.

Previous correction date: Correct immediately.

2.33 (b) (3) REPEAT ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

Seventy six goats being used at the facility were segregated from the main herds at the time of the inspection for various medical reasons. Health records for eight of the 76 goats were examined and all eight of those were found to be incomplete as well as containing insufficient detail to ensure that accurate information was conveyed to the attending veterinarian. There were vague or no descriptions of conditions such as acute injuries, lameness, respiratory, urinary, or neurologic diseases of the animals. Goat 8603 was observed to be lame, however lameness was not noted on the medical record.

Daily observations of all animals to assess their well-being, appropriate documentation of those

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Feb-28-2011

Received By:

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

Date:

Title:

Apr-05-2011



Inspection Report

observations, and direct and frequent communication with the attending veterinarian regarding health issues are necessary to ensure that the animals at the facility receive timely and adequate veterinary care. A system should be in place to ensure that all animals are observed daily, any health problems are adequately documented, and the attending veterinarian is notified when necessary.

Previous correction date: Correct immediately.

Note:

An exit briefing was conducted with a facility representative.
Accompanied by Dr. Alexandra Andricos.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Feb-28-2011

Received By:

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

Date:

Title:

Apr-05-2011