



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: May-05-2010

2.40 (a) (2) DIRECT NCI ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE (DEALERS AND EXHIBITORS).

(a) Each dealer or exhibitor shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section.

(2) Each dealer and exhibitor shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

Animal 7575 was observed to have a large, approximately baseball sized tumor protruding from the cranioventral aspect of the neck. The tumor was draining and the right shoulder of the animal was streaked with the dried effusion. The animal shared the common hay feeder with eight other animals. When the animal ate from the feeder the tumor was observed to make contact with the side of the feeder thus exposing the hay and other animals to the effusion. According to the medical record two other tumors were identified on 3/30/2010. On 4/14/2010 the veterinarian recommended that the animal be moved to an isolation pen for animals with medical conditions. The attending veterinarian was asked about the animal during the inspection and he stated that he was waiting for permission to euthanize from the facility owner because the animal may have valuable antibodies to harvest prior to euthanasia.

The attending veterinarian asked for permission to euthanize an animal with multiple tumors on 4/14/2010 and as of 5/5/2010 the facility owner had not authorized the euthanasia. The attending veterinarian must have the authority to provide adequate veterinary care for the animals at the facility in order to prevent unnecessary suffering of those animals. This authority includes prompt euthanasia of animals with untreatable medical conditions. The facility should ensure that the attending veterinarian has the authority to perform humane euthanasia without waiting for permission from management.

Correct immediately.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Jun-22-2010

Received By:

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

Date:

Title:

Jun-25-2010



Inspection Report

2.40 (b) (2) **DIRECT NCI**

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

(b) Each dealer or exhibitor 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.

Inspectors identified several instances where appropriate methods to prevent, control, diagnose, and treat diseases and injuries were not used.

Animal 5558 was observed to be significantly lame on the left front foot. The animal was found leaning against a feeder and was reluctant to move. The animal was treated with an antibiotic, pain medication, and a topical medication on 4/14/2010. The health record did not state why or where the topical medication was used. The treatment was completed prior to 4/28/2010. On that date the attending veterinarian noted that the animal was still lame and should be monitored without treatment. A staff member at the facility stated that the veterinarian had ordered the medications discontinued in order to assess the status of the animal. There were no instructions given to the animal caretakers regarding how long the animal was to be monitored or at what point treatment for pain should be reinstated. There was no way to assess the status of the lameness as the health record only stated that the animal was lame.

Animal 6531 was observed to be depressed and have an increased respiratory rate during the inspection. The animal had been moved from the main herd to an isolation ward with other animals being treated for respiratory disease because it was lame. The last recorded daily observation was on 4/29/2010. The animal had 900 milliliters of blood harvested on 4/30/2010 and was exhibiting respiratory signs on 5/5/2010 during the inspection. Staff at the facility had not noticed the respiratory signs prior to the inspection. Animals with potentially infectious conditions should be isolated from other animals to prevent infectious diseases from spreading through the herd. Additionally, animals with stress secondary to injury and blood harvesting may be more susceptible to infectious disease making them more likely to become infected.

Health records of six animals with medical conditions were obtained and examined. All six animals were used for production and had blood harvested on multiple occasions to obtain antibodies. Despite the medical conditions and blood harvesting the facility failed to keep current weights on the animals. The weights never changed for any of the animals during the time they were used for production. Three of the six animals were smaller and had chronic respiratory conditions. 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.

Animal 9915 had a history of anemia and a chronic, nonspecific respiratory condition and yet a hematocrit was not checked prior to blood harvesting on 2/25/2010. A respiratory condition was noted to be improved on 12/2/2009 but

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was noted again on 4/10/2010 with the animal exhibiting labored breathing on 5/4/2010. Additionally, a hematocrit had not been obtained when the animal developed the last respiratory condition or after labored breathing was noticed on 5/4/2010.

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.

Correct immediately.

2.40 (b) (3) DIRECT NCI

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

(b) Each dealer or exhibitor 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.

Animal 5558 was observed to be significantly lame on the left front foot during the inspection on 5/5/2010. The animal was found leaning against a feeder and was reluctant to move. The animal was treated with an antibiotic, pain medication, and a topical medication on 4/14/2010. The health record did not state why or where the topical medication was used. The treatment was completed prior to 4/28/2010. On that date the attending veterinarian noted that the animal was still lame and should be monitored without treatment. A staff member at the facility stated that the veterinarian had ordered the medications discontinued in order to assess the status of the animal. An animal caretaker stated that there were no instructions given to the staff regarding how long the animal was to be monitored or at what point treatment for pain should be reinstated. Despite the continued lameness the staff did not contact the attending veterinarian to inquire about reinstating pain medication.

Sixty-two animals of one species being used at the facility were segregated from the main herds at the time of the inspection for various medical reasons. Health records for six of the sixty-two were examined and all were found to be incomplete as well as containing insufficient detail to ensure that accurate information was conveyed to the attending veterinarian. There were no descriptions of conditions such as lameness or respiratory disease for five of the animals, no measurements or descriptions of tumors found on one animal. On several occasions there were notations that treatment should be continued when the initial treatment was never discussed. Some entries contain contradictory statements or vague observations that are difficult to interpret.

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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.

Correct immediately.

Note:

An exit briefing was conducted with the licensee.
Accompanied by Dr. Alexandra Andricos, DVM, VMO.

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

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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: May-05-2010

2.31 (d) (1) (i)

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.

Two animals with chronic medical issues continued to be used for antibody production resulting in discomfort, distress, and pain to those animals.

Animal 5558 was observed to be lame at the time of the inspection. Health records were obtained starting on 6/24/2009. The animal had been isolated from the healthy animals at some time prior to that date for an unknown condition and was placed with other animals with health issues. The animal had blood harvested for antibody production on 7/20/2009 and was deemed by the attending veterinarian to have "bad conformation" requiring continued segregation on 8/5/2009. Blood was harvested again on 8/25/2009, 11/12/2009, and 3/24/2010. On 4/13/2010 the animal was observed to be lame on the left front leg and was treated with pain killers and antibiotics on 4/14/2010. Medications were discontinued at some point prior to 4/28/2010. During the inspection the animal was reluctant to move when approached and was leaning the left shoulder on a feed bunker. When the animal did move it was significantly lame on the left front leg and was not being treated for pain.

Animal 10049 was observed to have a cough, an increased respiratory rate, and a nasal discharge during the inspection. The animal had been treated with different antibiotics or had antibiotic treatment extended at least 13 times for respiratory problems between 4/28/2009 and blood harvesting on 11/12/2009. At least three additional courses of antibiotics were given between 11/12/2009 and the date of inspection.

Continuing to use these animal for antibody production with their history of medical conditions caused

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them unnecessary discomfort, distress, and pain. A system should be in place to ensure that animals are appropriately assessed for suitability for production. Animals with chronic and significant medical conditions are not suitable subjects for antibody production.

Correct immediately.

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

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:

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Note:

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Accompanied by Dr. Alexandra Andricos, DVM, VMO.

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