



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: Mar-06-2012

2.40 (b) (3) **REPEAT 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.

Goat #9752 was isolated from the main herd due to poor condition. The poor condition was noticed on the date the goat was due to undergo blood collection, February 22, 2012. On the day of the inspection the animal was found to have a generalized skin condition with large areas of hair loss. The skin appeared crusty with open and scabbed lesions. The attending veterinarian had not been informed of the animal's condition and it had received no treatment in the 13 days since the goat had been isolated. Additionally, the medical record only stated that the animal was in poor condition and the skin condition was never added to the medical record.

Goat #14881 was observed to be in poor condition during the inspection. The last entry in the medical record by employees was 1/12/12 even though the animal had a history of chronic lameness and poor condition. The last veterinary entry in the medical record was 9/9/11.

When a large herd of approximately 1,000 goats was inspected one goat was observed standing apart from the others at the beginning of the inspection. After inspecting the goats in the barn and adjacent large paddock the same goat, #12028, was still standing apart from the others. Husbandry staff had not noticed the abnormal behavior. The goat was removed from the herd at that time by the attending veterinarian.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Apr-02-2012

Received By:

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

Date:

Title:

Apr-10-2012



Inspection Report

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.

Notes:

An exit briefing was conducted with a facility representative.
This inspection was focused on goats only.
Accompanied by Dr. Pam Smith and Dr. Carol Clarke.

Prepared By:

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

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Received By:

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Apr-10-2012



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: Mar-06-2012

2.31 (c) (7) **REPEAT**

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.

According to the IACUC approved protocol for the collection of whole blood in goats, the volume of blood to be collected for antibody production is determined by the body weight of the animals. The protocol states that 1 - 1.5 % of the body weight may be collected, thus implying that the animals should be weighed prior to having blood collected. The facility SOP for blood collection also stated that the staff should check the Weight List prior to collection and that "Each animal that weighs 135 lbs. or less will be reweighed before it is bled." None of the 95 goats bled the day of the inspection were weighed before being bled. Seventy five of the 95 goats weighed 135 pounds or less and thus should have been weighed if the instructions in the SOP were followed. Eleven of the 95 goats were weighed after being bled at the request of the inspectors and all 11 had lost weight since their last collection. Seven of the 11 were overdrawn using the volumes specified in the SOP. Three were overdrawn using the upper limit of 1.5% of body weight described in the protocol.

Failure to weigh the animals prior to blood collection constitutes an unapproved significant change to the approved protocol. A system should be in place to 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: April 15, 2011.

Prepared By:

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

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Title: VETERINARY MEDICAL OFFICER Inspector 5039

Mar-16-2012

Received By:

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

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Inspection Report

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 current IACUC approved protocol calls for whole blood collection in goats of "1 - 1.5 % of body weight..." citing an internet reference in support of the figures. The reference was a page from Duke University entitled "Guidelines for Blood Collection Procedures." According to this site the maximum 1.5% volume is safe for one time blood collection, not serial collections as performed at the facility:

"In general the volume of blood removed at any one bleeding should not exceed 1.5% of body weight (assuming that 1 ml of blood weighs 1 gram)." The Duke site continues by saying: "If blood is collected at repeated intervals, much less volume should be collected at any one time to avoid serious hematological problems. The following guidelines are recommended. If blood is collected at two week intervals, 10% of the animal's total calculated blood volume may be collected at one time. If blood is collected at four week intervals, or less frequently, 15% of the animal's total blood volume may be safely collected at one time."

This additional information provided by the Duke site was not incorporated into the protocol. The protocol also 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% of body weight figure and be expected to have additional blood collected in four weeks, prior to full recovery from the previous collection. Thus a 100 pound goat could have 750 ml of blood collected using 1.5% (+10%) body weight. Using 15% of the total blood volume to determine the maximum amount that can be safely collected the goat could have a maximum of 477 ml of blood collected. In fact, the facility had been collecting blood at up to 1.5% of body weight at two week intervals until January 2012. After monitoring hematocrit values and finding hematological problems the facility now collects blood no more frequently than four week intervals.

Eleven of the 95 goats undergoing blood collection on the day of the inspection were weighed after being bled at the request of the inspectors and all 11 had lost weight since their last collection. Seven of the 11 were overdrawn using the SOP volumes. Three were overdrawn using the upper limit of 1.5% of body weight described in the protocol. Using the 15% of total blood volume allowed by the Duke reference, all 11 were overdrawn.

Goat 5020 was extremely thin and lame on the day of the inspection. In 2007 the goat weighed 207 pounds. It was last weighed on 2/28/12 at 118 pounds. The goat was treated for chronic arthritis and on 6/17/11 was noted to be reluctant to walk. On 6/27/11 an employee noted that the goat was "Lame. Hind legs. Walks slowly and stiff." The goat had whole blood collected 14 times between 10/20/2008 and 3/14/11. The goat was then changed to plasma collection and has had plasma collected on a nearly

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weekly basis since that time. On 8/15/11 a consultant veterinarian ordered that the animal be treated with a non-steroidal anti-inflammatory drug on the day of plasma collection due to persistent arthritis. The medical record never references the weight loss although the animal was weighed several times. Since that date, there are repeated notes of no change until 10/31/11 through 11/27/11 when the employee record states "No clinical signs of illness." There are no additional medical records after 11/27/11 although the goat was very thin and still lame during the inspection.

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. Additionally, using animals in pain and/or poor health for blood or plasma collection does not avoid or minimize discomfort, distress, and pain to the animals.

Previous correction date: Correct immediately.

2.31 (d) (1) (vi)

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.

(vi) The animals' living conditions will be appropriate for their species in accordance with part 3 of this subchapter, and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

Several goat kids were observed inside metal hay feeders. One kid was seen attempting to exit a feeder and was wedged between the metal bars. The metal feeders being used at the facility are inappropriate as constructed for young goats. Feeders should be constructed so that the animals cannot become entrapped or injured.

Correct by May 10, 2012.

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2.31 (e) (3)

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.

The IACUC approved protocol for the use of goats contains an incomplete description of the proposed use of animals undergoing plasma collection. The protocol only contains a total maximum amount of plasma (up to 1650 ml) to be collected without regard to the weight of the goats. The description of whole blood collection contains a maximum amount per kilogram of body weight. The normal plasma volume of goats can range from approximately 53 to 60 ml/kg. Thus smaller goats at the facility that weigh under 50 kg could have total plasma volumes of less than 2400 ml, and be expected to lose more than two-thirds of their plasma volume. An employee at the facility stated that plasmapheresis goats receive fluids to replace some of fluid removed by the procedure. Fluid replacement, including route of replacement, amount, and type of fluid is not addressed by the protocol. In addition, the protocol states that plasmapheresis is performed on goats "...if health related issues would indicate plasmapheresis is preferential to conventional blood collection methods." Because plasmapheresis is performed on animals with health issues, a complete description should include measures taken to ensure that the amounts of plasma collected on those animals is limited so as to avoid detrimental effects.

The IACUC is responsible for reviewing all aspects of animal care and use, and for evaluating protocols in order to ensure compliance with the Animal Welfare Act. In order to properly accomplish this function, the IACUC must be aware of all procedures being conducted. It is the responsibility of the IACUC to ensure that protocols contain complete descriptions of proposed activities involving the use of animals prior to approval of the activities.

Correct by May 30, 2012.

2.33 (b) (3)

REPEAT DIRECT NCI

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

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Accompanied by Dr. Pam Smith and Dr. Carol Clarke.

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