Inspection Report

SANTA CRUZ BIOTECHNOLOGY, INC.

Customer ID: **1344**
Certificate: **93-R-0380**
Site: 002
SANTA CRUZ BIOTECHNOLOGY, INC.

2145 DELAWARE AVENUE

SANTA CRUZ, CA 95060

Type: ROUTINE INSPECTION
Date: Sep-26-2012

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.

Three goats used for the collection of plasma by plasmapheresis were showing signs of and being treated for chronic health conditions that could cause the animals discomfort, distress, and/or pain. Using the animals for antibody production during periods of illness could be expected to exacerbate discomfort, distress, or pain already being experienced by the animals.

Goat #4349 had a nasal discharge and was observed repeatedly tossing and shaking its head. There were numerous flies present which may have been a contributing factor to the head tossing. The goat had been kept in the plasmapheresis enclosure since at least 2007. Sinus issues were first mentioned on the medical records on May 21, 2012. Plasma was collected eight times in the four months since the condition was documented and while the goat was being treated. Between November of 2007 and June 2012 plasma was collected from this goat 160 times, for an average of approximately 2.76 times per month before the respiratory condition was documented and two times per month afterwards.

Goat #13310 had a history of chronic, intermittent respiratory disease since November of 2010 and had a bilateral nasal discharge at the time of the inspection. The goat was used for plasmapheresis starting in March of 2011 and was collected 24 times in the following 24 months. On some occasions plasma was collected while the goat was showing signs of and being treated for respiratory disease.

Goat # 3748 was geriatric and in poor condition with an abnormal, stiff gait. The goat had a history of chronic anemia and was diagnosed with arthritis in June of 2012. Plasma was collected twice in September 2012 despite the low hematocrit and arthritis. Plasma was also collected when the goat was lame on a

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front leg in 2011. Standing in a stanchion for approximately one hour per session for plasmapheresis could be expected to cause increased discomfort, distress, and/or pain in a goat with lameness or arthritis.

The IACUC approved protocol for plasma collection states: "Before plasmapheresis is performed, an animal is observed to verify it is suitable condition to undergo the procedure." However, the protocol does not define what a suitable condition is, or what an unsuitable condition might be. Using animals in poor health for blood or plasma collection does not avoid or minimize discomfort, distress, and pain to the animals. The IACUC should assure that there are clear guidelines as to the suitability of animals for use under the protocol, and the facility should avoid using animals in poor health or condition when the collection procedures themselves or physiologic impact of collecting blood or plasma may lead to discomfort, distress, or pain.

Previous correction date: Correct immediately.

2.33 **REPEAT DIRECT NCI**

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.

Goat #9563 was thin on the day of the previous August 23, 2012 inspection with prominent ribs, spinal processes, pelvis, and shoulders. The poor condition of this animal was not identified by staff until two days prior to the inspection. At that time it was moved from the main herd to a smaller isolation area. The goat was euthanized on August 29 due to respiratory disease that failed to improve.

Goat #10215 was in poor condition with prominent ribs, spinal processes, and pelvis. The goat also had a small open wound that appeared to be an abscess that was attracting flies. According to staff the goat's condition was first noticed on that same day, the day of the inspection. According to facility records the goat's condition was first observed when it was brought in to have blood collected that day.

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 are. 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.

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3.125 (a)

FACILITIES, GENERAL.

3.125 Facilities, general.
(a) Structural strength. The facility must be constructed of such material and of such strength as appropriate for the animals involved. The indoor and outdoor housing facilities shall be structurally sound and shall be maintained in good repair to protect the animals from injury and to contain the animals.

In the pens that house goats used for plasmapheresis collection, there were feeders with exposed metal ends that could cause injury. One long, horizontal plastic feeder has one exposed nail that protrudes about one inch. In another part of the same feeder there are three nail heads that are elevated, and could be sharp, and also suggest inadequate structural strength of the feeder. The wooden base for the feeder is made of two-by-fours, and there are large gaps between some of the joints, suggesting that the feeder could collapse and reveal more exposed metal nails. On the fence there are plastic horizontal supplement feeders attached with wire. In several places the wire is twisted around the wire panel fence, and it has many exposed and protruding ends projecting into the animal enclosure and measuring up to two inches long. Two welds on a large metal hay feeder were also broken resulting in loose metal rods that could cause injury.

Animals could become injured from sharp objects, or structures that are deteriorating. Animal enclosures should be free of sharp objects that could cause injury, and maintained in good repair so as to prevent potential injuries.

Correct by November 15, 2012.

3.129 (b)

FEEDING.

(b) Food, and food receptacles, if used, shall be sufficient in quantity and located so as to be accessible to all animals in the enclosure and shall be placed so as to minimize contamination. Food receptacles shall be kept clean and sanitary at all times.

A food receptacle in the W5 barn was contaminated with feces. Feces and flies were observed in a hay feeder used by several goats. Feeders should be kept clean and sanitary at all times so that the food is palatable and without contamination.

Correct by November 15, 2012.

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3.131 (a)

SANITATION.

(a) Cleaning of enclosures. Excreta shall be removed from primary enclosures as often as necessary to prevent contamination of the animals contained therein and to minimize disease hazards and to reduce odors.

An excessive amount of excreta was present in a paddock outside the W2 barn. Goat feces were present throughout the enclosure. In some areas the ground was completely covered in feces. Staff stated that the paddock was cleaned weekly. A large number of flies were also observed on and around the animals in that paddock and the animals in an adjacent paddock. The adjacent paddock was cleaned daily and did not contain an excessive amount of excreta. Animal enclosures should be cleaned as often as necessary to prevent contamination of the animals, minimize disease hazards, and to reduce odors.

Correct by November 15, 2012.

3.131 (d)

SANITATION.

(d) Pest control. A safe and effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

An excessive number of flies were present in goat paddocks outside of the W2 and W5 barns. The facility had no fly control measures in place for those areas with the exception of one fly trap in a W2 paddock. Flies may lead to food contamination, spread of disease, and distress to the animals. An effective fly control program should be in place to reduce the number of flies in the outdoor enclosures.

Correct by November 15, 2012.

An exit briefing was conducted with a facility representative.
This was a focused inspection involving only the W2 and W5 barn goats.
Accompanied by Dr. Pam Smith.

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