



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: Oct-31-2012

2.4

NON-INTERFERENCE WITH APHIS OFFICIALS.

Sec. 2.4 Non-interference with APHIS officials.

A licensee or applicant for an initial license shall not interfere with, threaten, abuse (including verbally abuse), or harass any APHIS official in the course of carrying out his or her duties.

A large production barn and herd of goats was discovered at the facility nine miles south of the ranch office. Staff members at the facility, including the previous attending veterinarian, a previous resident veterinarian, and a previous veterinary technician were all asked during past inspection if goats were being housed beyond the owner's residence. Those staff members always stated that there were no goats being housed past the owner's residence, which is on the other side (south-east) of the ranch office. The previous attending veterinarian was last asked that question at an inspection earlier in 2012.

The barn, currently named H7 (changed from Lake Ranch at some time between the May 24, 2012 and June 26, 2012 inspections), is not new construction and appears to be the same approximate age as other barns at the facility. Staff at the facility stated that animals with health problems are always transported from Lake Ranch/H7 to the main barns for treatment. A partial review of individual goat records obtained from the facility during inspections between May 2010 and August 2012 found animals with home locations of Lake Ranch or H7 being treated for health problems at one of the main barns. Thus the barn was in use for at least the last 2.5 years.

Several staff members as well as management at this facility failed to inform APHIS officials of the location of a site where regulated animals were housed and regulated activities (blood collection for antibody production) were taking place. The existence of the site was denied even when directly asked during APHIS inspections. By failing to disclose this information the licensee has interfered with APHIS officials and prevented them from carrying out their responsibility to enforce the Animal Welfare Act.

Correct immediately.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Dec-07-2012

Received By:

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

Date:

Title:

Dec-07-2012



Inspection Report

2.8

NOTIFICATION OF CHANGE OF NAME, ADDRESS, CONTROL, OR OWNERSHIP OF BUSINESS.

Sec. 2.8 Notification of change of name, address, control, or ownership of business.

A licensee shall promptly notify the AC Regional Director by certified mail of any change in the name, address, management, or substantial control or ownership of his business or operation, or of any additional sites, within 10 days of any change.

A herd of 841 goats that is currently being used for antibody production was discovered during the inspection. The herd was located approximately nine miles past the main barns. The existence of this herd and the barn (currently called H7) where they reside, which includes a blood collection installation, was previously unknown to USDA, although it has been in use for some time. The full-time onsite veterinarian stated that the veterinary staff does not visit this herd, and the office staff said that any sick goats at H7 are brought to the main barns for treatment. Office staff also stated that the barn name had been changed from Lake Ranch to H7 at some time in the past. A previous attending veterinarian was asked by the APHIS inspector during an earlier 2012 inspection if the facility was housing any goats in the direction of the H7 barn. She answered that no goats were housed in that direction. Other facility personnel have been asked intermittently over the past several years if goats were housed in that direction and have also stated that no goats were being kept in that direction.

The dealer failed to notify the AC Regional Director of the existence of an entire building and group of animals being used under their license. The facility should ensure that the location of all animals being used under their registration are reported to the appropriate APHIS officials in a timely manner.

Correct immediately.

2.40

(b) (2)

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:

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care.

A herd of 841 goats, identified as "H7", that is currently being used for antibody production was discovered during the inspection. The existence of this herd and the barn where they reside, which includes a blood collection installation, was previously unknown to USDA, although it has been in use for some time. A full-time onsite veterinarian stated that the veterinary staff does not visit this herd, and the office staff said that any sick goats at this site are brought to the main site for treatment.

During the inspection twelve goats with significant health concerns were identified for records review:

10073-Poor condition with a bilateral crusty nasal discharge. Also anemia, with a production hematocrit

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recorded on 9/4/12 at 18 percent.
9873-Nasal discharge.
9044-Poor condition, with bilateral nasal discharge.
9912-Nasal discharge.
6350-Stiff gait, bilateral nasal discharge, poor condition.
8904-Significant right front leg lameness, nasal discharge, and a cough.
9500-Significant right front leg lameness.

Additionally, these goats were observed to be in poor condition, with protruding spinal processes;
8820, 10059, 9099, 6006, and 9656.

According to the records and the statement of the full-time staff veterinarian, none of these animals had received any treatment or veterinary observation. Failure to provide appropriate veterinary care could jeopardize the health and well-being of the animals. The facility should ensure that their program of veterinary care appropriately addresses the medical needs of all animals under their care.

Previous correction date: correct immediately.

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 #10215 was in poor condition on the previous September 26, 2012 inspection. This goat is receiving veterinary care, and showing improvement.

Records were requested on twelve goats from the H7 herd that were in poor condition and /or showed signs of serious medical issues. These were goats # 10073, 9656, 10059, 6350, 9873, 9912, 8904, 6006, 9099, 9500, 8820, and 9044. There is no evidence in the records that the husbandry staff observed any of these conditions, provided any treatment, or notified the veterinary staff regarding these problems. Of the twelve records examined, only three goats had ever had a "Detailed Ranch Observation" notation, or any other treatment or veterinary consultation recorded, and the most recent such notation was in December 2011 on goat # 8820.

Failure to observe the animals on a daily basis and report any concerns to the veterinary staff could be detrimental to their health and well-being. Daily observation of all animals to assess their well-being,

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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.

3.131 (c)

SANITATION.

3.131: Sanitation

(c) Housekeeping. Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. Accumulations of trash shall be placed in designated areas and cleared as necessary to protect the health of the animals.

Two pieces of pvc pipe and an approximately 3" piece of rusted metal were found in a large paddock with hay feeders outside of barn H7. A large pile of metal cable was observed in the pasture beyond the paddock, which housed over 800 goats at the time of the inspection. A portion of the cable fencing in the pasture was also broken and the cable was coiled on the ground. Goats were observed walking over and through the cables.

Trash and foreign objects in animal enclosures may cause injury to the animals. The facility should ensure that their staff monitor enclosures for unwanted and broken items, and remove and repair those items in a timely manner.

Correct by November 15, 2012.

An exit briefing was conducted with a representative of the facility.
This was a focused inspection of barns W5 and H7
Accompanied by Dr. Pam Smith
This is an electronic copy of the report done on October 31, 2012 on site 001.

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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: Oct-31-2012

2.25 (c)

REQUIREMENTS AND PROCEDURES.

Sec. 2.25 Requirements and procedures.

(c) No registrant or person required to be registered shall interfere with, threaten, abuse (including verbally abuse), or harass any APHIS official who is in the course of carrying out his or her duties.

A large production barn and herd of goats was discovered at the facility nine miles south of the ranch office. Staff members at the facility, including the previous attending veterinarian, a previous resident veterinarian, and a previous veterinary technician were all asked during past inspections if goats were being housed beyond the owner's residence. Those staff members always stated that there were no goats being housed past of the owner's residence, which is on the other side (south-east) of the ranch office. The previous attending veterinarian was last asked that question at an inspection earlier in 2012.

The barn, currently named H7 (changed from Lake Ranch at some time between the May 24, 2012 and June 26, 2012 inspections), is not new construction and appears to be the same approximate age as other barns at the facility. Staff at the facility stated that animals with health problems are always transported from Lake Ranch/H7 to the main barns for treatment.

A partial review of individual goat records obtained from the facility during inspections between May 2010 and August 2012 found animals with home locations of Lake Ranch or H7 being treated for health problems at one of the main barns. Thus the barn was in use for at least the last 2.5 years.

Several staff members as well as management at this facility failed to inform APHIS officials of the location of a site where regulated animals were housed and regulated activities (blood collection for antibody production) were taking place. The existence of the site was denied even when directly asked during APHIS inspections. By failing to disclose this information the registrant has interfered with APHIS officials and prevented them from carrying out their responsibility to enforce the Animal Welfare Act.

Correct immediately.

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2.30 (c) (1)

REGISTRATION.

Sec. 2.30: Registration

(c) Notification of change of operation.

(1) A research facility shall notify the AC Regional Director by certified mail of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, within 10 days after making such change.

A herd of 841 goats that is currently being used for antibody production was discovered during the inspection. The herd was located approximately nine miles past the main barns. The existence of this herd and the barn (currently called H7) where they reside, which includes a blood collection installation, was previously unknown to USDA, although it has been in use for some time. The full-time onsite veterinarian stated that the veterinary staff does not visit this herd, and the office staff said that any sick goats at H7 are brought to the main barns for treatment. Office staff also stated that the barn name had been changed from Lake Ranch to H7 at some time in the past. A previous attending veterinarian was asked by the APHIS inspector during an earlier 2012 inspection if the facility was housing any goats in the direction of the H7 barn. She answered that no goats were housed in that direction. Other facility personnel have been asked intermittently over the past several years if goats were housed in that direction and have also stated that no goats were being kept in that direction.

The research facility failed to notify the AC Regional Director of the existence of an entire building and group of animals being used under their registration. The facility should ensure that the location of all animals being used under their registration are reported to the appropriate APHIS officials in a timely manner.

Correct immediately.

2.31 (c) (7)

REPEAT DIRECT NCI

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31: 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.

Records were requested on twelve goats in the newly discovered H7 herd that were in poor condition and / or had other medical issues. Goat ID numbers are: 10073, 9656, 10059, 6350, 9873, 9912, 8904, 6006, 9099, 9500, 8820, and 9044.

According to the records provided, while the most recent whole blood collections do show a recorded hematocrit prior to collection, all twelve goats have had multiple whole blood collections without a recorded hematocrit check. Whole blood collections without hematocrits were performed in early 2012, 2011, and earlier. The protocol specifies that the animals must have a specific minimum packed cell

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volume at the time of whole blood collection. This cannot be verified without checking the hematocrit near the time of collection. Collecting whole blood without knowing the hematocrit could mean that anemic animals are collected, which could be detrimental to their health and well-being.

According to the records provided, while the most recent whole blood collections do show a recorded weight prior to collection, all twelve goats have had multiple whole blood collections without a recorded weight. Whole blood collections without recorded weights were performed in early 2012, 2011, and earlier. The protocol specifies that the animals must have the weight checked at the time of whole blood collection in order to calculate the volume of blood to be collected, and this cannot be verified without checking the weight near the time of collection. Collecting whole blood without knowing the weight could result in over-collection, which could be detrimental to the health and well-being of the animal.

Failure to check hematocrits and 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: Correct Immediately.

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

Sec. 2.33: 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;

A herd of 841 goats, identified as H7, that is currently being used for antibody production was discovered during the inspection. The existence of this herd and the barn where they reside, which includes a blood collection installation, was previously unknown to USDA, although it has been in use for some time. A full-time onsite veterinarian stated that the veterinary staff does not visit this herd, and the office staff said that any sick goats at this site are brought to the main site for treatment.

During the inspection twelve goats with significant health concerns were identified for records review:

10073 Poor condition with a bilateral crusty nasal discharge. Also anemia, with a production hematocrit recorded on 9/4/12 at 18 percent.

9873 Nasal discharge.

9044 Poor condition, with bilateral nasal discharge.

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6350 Stiff gait, bilateral nasal discharge, poor condition.

8904 Significant right front leg lameness, nasal discharge, and a cough.

9500 Significant right front leg lameness.

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Additionally, these goats were observed to be in poor condition, with protruding spinal processes: 8820, 10059, 9099, 6006, and 9656.

According to the records and the statement of the full-time staff veterinarian, none of these animals had received any treatment or veterinary observation. Failure to provide appropriate veterinary care could jeopardize the health and well-being of the animals. The facility should ensure that their program of veterinary care appropriately addresses the medical needs of all animals under their care.

Previous correction date: Correct immediately.

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

2.33 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 #10215 was in poor condition on the previous Sept. 26, 2012 inspection. This goat is receiving veterinary care, and showing improvement.

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Failure to observe the animals on a daily basis and report any concerns to the veterinary staff could be detrimental to their health and well-being. Daily observation 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.

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3.131 (c)

SANITATION.

3.131: Sanitation

(c) Housekeeping. Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. Accumulations of trash shall be placed in designated areas and cleared as necessary to protect the health of the animals.

Two pieces of pvc pipe and an approximately 3" piece of rusted metal were found in a large paddock with hay feeders outside of barn H7. A large pile of metal cable was observed in the pasture beyond the paddock, which housed over 800 goats at the time of the inspection. A portion of the cable fencing in the pasture was also broken and the cable was coiled on the ground. Goats were observed walking over and through the cables.

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Accompanied by Dr. Pam Smith.

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