



JUN 10 2005

United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Marketing &  
Regulatory  
Programs Business  
Services

4700 River Road  
Riverdale, MD  
20737

Santa Cruz Biotechnology, Inc.  
2161 Delaware Avenue  
Santa Cruz, CA 95060

Dear Sir(s):

The Animal and Plant Health Inspection Service (APHIS) enforces regulations in order to protect the health and care of animals, plants, and agricultural industry. Violations of these regulations jeopardize the animal and plant health systems that are vital to protect American agriculture.

Our investigation shows that you have violated Federal Regulations as described on the enclosed Civil Penalty Stipulation Agreement form. APHIS laws and regulations provide for administrative and criminal penalties to enforce these regulatory requirements. The amount of the monetary penalty, or possible criminal charges, depends on the number and severity of the violations.

The Secretary of Agriculture may assess a civil penalty for such violations after notice and an opportunity for a hearing. However, you may waive your right to a hearing and settle this matter by paying \$4,600 and signing the agreement form. You may voluntarily accept this reduced agreement to avoid further action.

Please pay the civil penalty by certified check or money order made payable to the Treasurer of the United States. Write the Case Number (CA05047-AC) on your check or money order and mail it with the signed agreement form to:

USDA, APHIS, (General) (CA05047-AC)  
P. O. Box 952180  
St. Louis, MO 63195-2180

If we do not receive your signed stipulation agreement and payment within 30 days, we will seek higher civil or criminal penalties for each violation. You may contact our office at telephone number (301) 734-8684 if you have any questions.

Sincerely,

Allison Khroustaley  
Assistant Director, Enforcement  
Investigative and Enforcement Services

Enclosure

cc: T. Fordhal, IES, WR  
D. Head, IES, AR

Dr.R. Gibbens, AC., WR

APHIS:IES:JSedgwick:ram:734-8759:06/09/05:CA05047-AC Santa Cruz



Safeguarding American Agriculture  
APHIS is an agency of USDA's Marketing and Regulatory Program

An Equal Opportunity Provider and Employer

AWA Docket 12-0536/AWA Docket 15-0023

CX 5  
1 of 6

**Investigative and Enforcement Services**

**Settlement Agreement**

USDA, APHIS, IES  
 4700 River Road, Unit 85  
 Riverdale, MD 20737  
 Phone: (301) 734-8684  
 Fax: (301) 734-4328

**CASE NUMBER** CA05047-AC  
**DUE ON OR BEFORE** July 10, 2005  
**CONTACT** Janice Sedgwick  
**PHONE** (301) 734-8759

**RESPONDENT:**  
 Santa Cruz Biotechnology, Inc.  
 2161 Delaware Avenue  
 Santa Cruz, CA 95060

DATE	CITATION	DESCRIPTION
(SEE ATTACHED PAGES)		

**PENALTY** \$4,600

**TERMS**

Titles 7, 15, 19, and 21 of the United States Code authorize the Secretary of Agriculture to impose civil penalties and other sanctions to resolve violations after providing notice and opportunity for a hearing.

You may waive your right to a hearing and agree to pay the specified civil penalty in settlement of this matter. If you do not agree to the specified penalty, a complaint shall be issued charging you with the violation(s) and seeking higher penalties. You will have the opportunity for a hearing before an Administrative Law Judge to present your case.

I acknowledge that I have been given an opportunity for a hearing and waive such hearing. I neither admit nor deny the violations cited above and agree to pay the civil penalty in full settlement of this matter.

**Signature of Respondent:**

**Date:**

**PAYMENT RECORD - FOR IES USE ONLY**

Payment Type	Date	Amount	Signature of IES Representative

<u>DATE</u>	<u>CITATION</u> 9 CFR	<u>DESCRIPTION</u>
10 OCT 02	3.56(a)(1)	<b>Cleaning of primary enclosures.</b> There was an accumulation of feces under the rabbit enclosures and no procedures for cleaning and sanitizing the enclosures.
	3.56(b)(1)	<b>Sanitation of primary enclosures.</b> The rabbit enclosures were not sanitized.
	3.56(d)	<b>Pest control.</b> There were many flies around the animal enclosures.
	2.31(b)(3)(ii)	<b>Institutional Animal Care and Use Committee (IACUC).</b> A non-affiliated community member had not attended IACUC meetings for 18 months.
	3.54(a)	<b>Feeding.</b> There were several open bags of rabbit feed in the storage area.
06 JUL 04	2.33(a)(1)	<b>Attending veterinarian and adequate veterinary care.</b> No written program of veterinary care was available for review for the rabbits.
	2.33(b)(1)	<b>Attending veterinarian and adequate veterinary care.</b>
	2.33(b)(2)	Goat #1598 was unable to rise and had been lame since 8-17-02.
	2.33(b)(3)	The goat was also anemic on 6-4-04, and there was no record of treatment.
	2.33(b)(4)	Goats #1598, 499, and 1402 had health problems that were not communicated to the attending veterinarian.
2.33(b)(5)	Goats #1598, 499 and 1402 had health problems but were still used for antibody production.	
27 SEP 04	2.31(c)(7)	<b>Institutional Animal Care and Use Committee (IACUC).</b> Failed to have the IACUC review and approve changes in protocols, collected plasma from sick and debilitated goats, and failed to follow approved treatment regimens.
	2.31(d)(1)(viii)	Failed to have the staff adequately trained to handle rabbits and perform procedures.
	2.31(e)(1)	Made significant change in the numbers of rabbits used for the production of antibodies. The protocol authorized the use of 80 rabbits; and at the time of the inspection, 1,024 rabbits were being used.
	2.31(e)(2)	Made significant change in an ongoing activity without providing rationale in the protocol that addresses the appropriateness of the number of animals being used. The rationale for using large animals was contradicted by the use of large numbers of small animals.
	2.33(a)(2)	<b>Attending veterinarian and adequate veterinary care.</b> Failed to follow the recommended treatment of the veterinarian. Bleed Report, dated 9-27-04, shows that blood was collected from an animal after veterinarian recommended ceasing blood collection.
	2.33(b)(2)	There was no record for treatment of lesions on animal E4, and animal 431 had low hematocrit. There was no record that the veterinarian was contacted for approximately 90 days. Animal #713 was repeatedly used for blood and plasma production after low hematocrit was found.
	2.33(b)(4)	Used unapproved forms of euthanasia (procaine penicillin and gunshot).
	3.56(a)(1)	<b>Cleaning of primary enclosures.</b> Several rabbit cages contained areas with caked feces and hair.

3.127(a)

**Shelter from sunlight.**

Two miniature donkeys were housed in a pasture that provided no structures for shade.

3.130

**Watering.**

Several water troughs in pastures housing goats had a build-up of algae.

3.131(c)

**Sanitation.**

Trash, including baling twine and pieces of pipe hose, was found in pastures housing goats.

09 DEC 04 2.31(c)(7)

**Institutional Animal Care and Use Committee (IACUC).**

Failed to have IACUC review and approve changes in protocols. Blood was not being harvested in accordance with the protocol on six of the miniature donkeys.

### Investigative and Enforcement Services

# Settlement Agreement

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I acknowledge that I have been given an opportunity for a hearing and waive such hearing. I neither admit nor deny the violations cited above and agree to pay the civil penalty in full settlement of this matter.

Signature of Respondent: *John R Stephenson*      Date: 7/8/05

#### PAYMENT RECORD - FOR IES USE ONLY

Payment Type	Date	Amount	Signature of IES Representative