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UNITED STATES DEPARTMENT OF AGRICULTURE

BEFORE THE SECRETARY OF AGRICULTURE

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In re:

Dkt. No. 12-0536

Santa Cruz Biotechnology, Inc.,

Respondent

)

Complaint

There is reason to believe that the respondent named herein has willfully violated the Animal Welfare Act, as amended (7 U.S.C. § 2131 et seq.), hereinafter referred to as the Act, and the regulations and standards (9 C.F.R. § 1.1 et seq.) issued pursuant to the Act, and, therefore, the Administrator of the Animal and Plant Health Inspection Service ("APHIS") issues this complaint alleging the following:

I

A. Santa Cruz Biotechnology, Inc., hereinafter referred to as respondent, is a California corporation whose address is 2145 Delaware Avenue, Santa Cruz, California 95060.

B. The respondent, at all times material hereto, was registered and operating as a research facility as defined in the Act and the regulations and was also registered and operating as a dealer as defined in the Act and the regulations.

C. The respondent has received a copy of the regulations and the standards issued pursuant to the Act and agreed in writing to comply with them.

II

A. On July 24, 2007, APHIS inspected respondent's premises and found that the respondent had failed to establish and maintain programs of adequate vet care that included daily observation of all animals to assess their health and well-being, in willful violation of sections 2.33(b) (3) and 2.40(b) (3) of the regulations (9 C.F.R. §§ 2.33(b) (3), 2.40(b) (3)).

B. On July 24, 2007, APHIS inspected respondent's premises and records and found that the respondent failed to have the Institutional Animal Care and Use Committee (IACUC) of the research facility review the procedures used involving animals to ensure that the principal investigator had considered alternatives to procedures that would cause more than momentary or slight pain or distress to the animals, and to have provided a written narrative description of the methods and sources, in violation of section 2.31(d) (1)(ii) of the regulations (9 C.F.R. § 2.31(d) (1)(ii)).

C. On July 24, 2007, APHIS inspected respondent's premises and records and found that the respondent failed to have the IACUC of the research facility review the procedures used involving animals to ensure that the principal investigator had considered alternatives to procedures that would cause more than momentary or slight pain or distress to the animals, and be performed with appropriate sedatives, analgesics or anesthetics, unless

withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time in willfull violation of section 2.31(d)(1)(iv)(A) of the regulations (9 C.F.R. § 2.31(d)(1)(iv)(A)).

D. On July 24, 2007, APHIS inspected respondent's facility and records and found the following willful violations of section 2.100(a) of the regulations (9 C.F.R. § 2.100(a)) and the standards specified below:

1. Respondent's employees failed to handle all animals as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm or unnecessary discomfort (9 C.F.R. § 2.131(b)(1)); and

2. On July 24, 2007, APHIS inspected respondent's premises and found that the respondent failed to handle all animals as expeditiously and carefully as possible in a manner that did not cause trauma, overhearing, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort(9 C.F.R. § 2.38(f)(1)).

III

A. On July 13, 2010, APHIS inspected respondent's premises and records and found that the respondent's employees were not properly trained in the proper care and handling for the various species of animals used by the facility, in violation of section 2.32(c)(1)(ii)) of the regulations (9 C.F.R. § 2.32(c)(1)(ii)).

B. On July 13, 2010, APHIS inspected respondent's premises and records and found that the respondent's employees were not properly trained in the proper use of anesthetics, analgesics and tranquilizers for any species of animals used by the facility, in willful violation of section 2.32(c) (3)) of the regulations (9 C.F.R. § 2.32(c) (3)).

C. On July 13, 2010, APHIS inspected respondent's premises and found that the respondent had failed to establish and maintain programs of adequate vet care that included appropriate methods to prevent, control, diagnose and treat disease and injuries, in willful violation of sections 2.33(b) (2) and 2.40(b) (2) of the regulations (9 C.F.R. §§ 2.33(b) (2), 2.40(b) (2)).

D. On July 13, 2010, APHIS inspected respondent's premises and found that the respondent had failed to establish and maintain programs of adequate vet care that included daily observation of all animals to assess their health and well-being, in willful violation of sections 2.33(b) (3) and 2.40(b) (3) of the regulations (9 C.F.R §§ 2.33(b) (3), 2.40(b) (3)).

E. On July 13, 2010, APHIS inspected respondent's facility and records and found the following willful violations of section 2.100(a) of the regulations (9 C.F.R. § 2.100(a)) and the standards specified below:

1. A sufficient number of respondent's employees were not adequately trained to maintain a professionally acceptable level of

husbandry practices (9 C.F.R. § 3.132).

IV

A. On February 8, 2011, APHIS inspected respondent's premises and records and found that the Institutional Animal Care and Use Committee (IACUC) did not 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, in willful violation of section 2.31(c)(7)) of the regulations (9 C.F.R. § 2.31(c)(7)).

B. On February 8, 2011, APHIS inspected respondent's premises and records and found that the IACUC did not insure that procedures involving animals will avoid or minimize discomfort, distress and pain to the animals, in willful violation of section 2.31(d)(1)(i) of the regulations (9 C.F.R. § 2.31(d)(1)(i)).

C. On February 8, 2011, APHIS inspected respondent's premises and found that the respondent failed to establish and maintain programs of adequate vet care that included appropriate methods to prevent, control, diagnose and treat disease and injuries, in willful violation of sections 2.33(b)(2) and 2.40(b)(2) of the regulations (9 C.F.R. §§ 2.33(b)(2), 2.40(b)(2)).

D. On February 8, 2011, APHIS inspected respondent's premises and found that the respondent had failed to establish and maintain programs of adequate vet care that included daily observation of all animals to assess their health and well-being, in willful violation

of sections 2.33(b)(3) and 2.40(b)(3) of the regulations (9 C.F.R. §§ 2.33(b)(3), 2.40(b)(3)).

V

A. On April 5, 2011, APHIS inspected respondent's facility and records and found the following willful violations of section 2.100(a) of the regulations (9 C.F.R. § 2.100(a)) and the standards specified below:

1. Food for the animals was not wholesome, palatable, and free from contamination and of sufficient quantity and nutritive value to maintain all animals in good health (9 C.F.R. § 3.129).

VI

A. On March 6, 2012, APHIS performed a partial inspection of the respondent's premises and records at the location referred to as site 1 and found that the respondent failed to establish and maintain programs of adequate veterinary care under the supervision and assistance of a doctor of veterinary medicine and failed to provide veterinary care to animals in need of care, in willful violation of section 2.40 of the regulations (9 C.F.R. § 2.40).

B. On March 6, 2012, APHIS inspected respondent's facility and records at the location referred to as site 2 and found the following willfull violation of the regulations:

1. The IACUC as an agent of the research facility failed to 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 (9 C.F.R. § 2.31(c)(7));

2. The IACUC failed to determine that the proposed activities or significant changes in ongoing activities ensured that procedures involving animals would avoid or minimize discomfort, distress, and pain to the animals (9 C.F.R. § 2.31(d)(1)(i));

3. The IACUC failed to determine that the animals' living conditions were appropriate for their species, that the living conditions contributed to the animals' health and comfort and that the housing, feeding and nonmedical care of the animals 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 (9 C.F.R. § 2.31(d)(1)(vi));

4. A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals did not contain a complete description of the proposed use of the animals (9 C.F.R. § 2.31(e)(3)); and

5. The respondent failed to establish and maintain programs of adequate veterinary care that includes daily observation of all animals to assess their health and well-being (9 C.F.R. § 2.33(b)(3)).

VII

A. On April 19, 2012 APHIS performed a limited inspection of the respondent's premises and records at the location referred to as site 2 and found the respondent failed to establish and maintain

programs of adequate veterinary care that included the availability of appropriate facilities, personnel, equipment, and services as necessary in willful violation of section 2.33(b)(1) of the regulations (9 C.F.R. § 2.33(b)(1)).

B. The respondent failed to establish and maintain programs of adequate veterinary care that includes daily observation of all animals to assess their health and well-being in willful violation of section 2.33(b)(3) of the regulations (9 C.F.R. § 2.33(b)(3)).

VIII

A. On May 2, 2012, APHIS inspected the respondent's premises and records and found that the respondent failed to establish and maintain programs of adequate veterinary care under the supervision and assistance of a doctor of veterinary medicine and failed to provide veterinary care to animals in need of care, in willful violation of section 2.40(b)(1) and (2) of the regulations (9 C.F.R. § 2.40(b)(1) and (b)(2)).

B. The respondent failed to establish and maintain programs of adequate veterinary care that included the availability of appropriate facilities, personnel, equipment, and services as necessary in willful violation of section 2.33(b)(1) of the regulations (9 C.F.R. § 2.33(b)(1)).

C. On May 2, 2012, APHIS inspected respondent's premises and found that the respondent had failed to establish and maintain programs of adequate vet care that included appropriate methods to

prevent, control, diagnose and treat disease and injuries, in willful violation of section 2.33(b) (2) of the regulations (9 C.F.R. §§ 2.33(b) (2)).

WHEREFORE, it is hereby ordered that for the purpose of determining whether the respondent has in fact violated the regulations and standards issued under the Act, this complaint shall be served upon the respondent. The respondent shall file an answer with the Hearing Clerk, United States Department of Agriculture, Washington, D.C. 20250-9200, in accordance with the Rules of Practice governing proceedings under the Act (7 C.F.R. § 1.130 et seq.). Failure to file an answer shall constitute an admission of all the material allegations of this complaint.

The Animal and Plant Health Inspection Service requests:

1. That unless the respondent fails to file an answer within the time allowed therefor, or files an answer admitting all the material allegations of this complaint, this proceeding be set for oral hearing in conformity with the Rules of Practice governing proceedings under the Act; and
2. That such order or orders be issued as are authorized by the Act and warranted under the circumstances, including an order:

(a) Requiring the respondent to cease and desist from violating the Act and the regulations and standards issued thereunder; and

(b) Assessing civil penalties against the respondent in accordance with section 19 of the Act (7 U.S.C. § 2149).

Done at Washington, D.C.
this 19th day of July, 2012

Acting

[REDACTED]
Administrator
Animal and Plant Health
Inspection Service

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