



<http://stopcovance.com/reports/resfrpacrpinsp20050516.htm>

Go

[5 captures](#)

9 Feb 07 - 24 Nov 11

JUN

2008

**COVANCE RESEARCH PRODUCT:
INC**

**310 SWAMPBRIDGE ROAD
P.O. BOX 7200
DENVER, PA 17517**

**Customer ID: 281
Certificate: 23-R-0007**

**Site: 009
COVANCE RESEARCH**

**Inspection
Type: ROUTINE INSPECTION
Date: MAY-16-2005**

2.31 (e) (2)

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 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:

2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

The IACUC approved protocol ANS # 1188 does not provide an adequate rationale for the appropriateness of the number of animals to be used in this study. The rationale for the number of animals needed for the original study which was approved for 10 animals in February 2004 was inadequate, stating only that ANS # 1188 was a "feasibility study" to gather preliminary information on the safety of the implants. An amended protocol was approved by the IACUC for 20 animals in March 2005, but also did not provide an adequate rationale that explained why 20 animals were needed for this study.

Justification for the number of animals to be used is important in order to ensure that the maximum amount of information is gained using the minimum number of animals. It is the responsibility of the IACUC to ensure that proposals, renewals, and significant changes involving animals contain rationales that adequately explain the appropriateness of the numbers of animals to be used in those activities.

Correct by December 15, 2005.

(3) A complete description of the proposed use of the animals.

The description of procedures conducted under protocol ANS # 1188, "Safety Evaluation of Chronic Placement of Implants for Upper Airway Stabilization," is inadequate. The size and composition of the devices being implanted in the tongues, palates, and pharyngeal walls are not discussed in the protocol. Additionally, the protocol does not provide an adequate description of postoperative care to be provided to the animals. There was no description of postoperative dietary needs or a timeframe for when the animals used in this study could be safely transported to the Pork Power facility.

Prepared By: *Marcy Rosendale*
MARCY ROSENDALE, V.M.O., USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER, Inspector ID: 5039

Received By: [Redacted]
Title: [Redacted]

Date:
MAY-17-2005

Date:
JUN-16-2005

8870

The IACUC is responsible for reviewing all aspects of animal care and use, and evaluating protocols in order to ensure compliance with the Animal Welfare Act and regulations. In order to properly accomplish this function, the IACUC must have a sufficient knowledge of the procedures being conducted. It is the responsibility of the IACUC to ensure that the investigator has provided a complete and thorough description of all proposed procedures.

Correct by December 15, 2005.

2.33 (b) (3)

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.

Several pigs at the Pork Power facility had overgrown claws. The claws were at a length that could interfere with the animal's normal movement. A system should be in place to ensure that appropriate methods are employed to prevent excessive growth of the claws and to treat individual animals with overgrown claws.

Correct by September 15, 2005.

Prepared By:

Marcy Rosendale, V.M.O.
MARCY ROSENDALE, V.M.O., USDA, APHIS, Animal Care

Title:

VETERINARY MEDICAL OFFICER , Inspector ID: 5039

Date:

MAY-17-2005

Received By:

[Redacted Signature]

Date:

JUN-16-2005

Title:

4 2 3 2005