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United States Department of Agriculture
Animal and Plant Health Inspection Service

JUN 27 2005

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INSPECTION REPORT

**COVANCE RESEARCH
PRODUCTS INC**

Customer ID: 281
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http://stopcovance.com/reports/resfrpacrpinsp20050603.htm

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Date: JUN-03-2005

- 2.31 (c)
- 2.31 (e X 2)
- 2.31 (e X 3)
- 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 of a protocol (Protocol 1188) reviewed indicated that the facility is not following the protocol as written. Weights are required every 3-4 days for 2 weeks after surgical procedures are performed and then weekly. There are no weights taken after the surgical procedure as required, nor are they taken weekly.

The protocol states that dogs must be over 1 year of age but has used dogs that are younger. Every part of this written protocol must be followed without change unless they have been IACUC approved prior to implementation.

Correct by July 30, 2005

(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;

Protocol ANS 1188 was identified as a pilot type of study. There were two species of animals used on the study and 10 animals going to be used by the investigator. There were no discussion of why 10 animals were selected for the study. An amendment to the study indicated that 11 animals had already been used, which was more than the initially approved number of animals, and that an increase of 10 animals would be required. It should have been identified during the amendment approval process that the investigator used more animals than the initial number of animals approved by the IACUC, and reasoning as to why this increase occurred without approval. The amendment did not indicate, species nor provide any supplemental materials to the IACUC as to the outcome of the 11 previous procedures. Any increase in numbers of animals must be justified prior to an IACUC approval.

Correct by July 1, 2005

(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: (3) A complete description of the proposed use of the animals;

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Several factors affecting the animal in Protocol ANS 1188 was not described to the IACUC; a description of the implant devices, size of the device nor the feeding regime after the device was placed in the animal. The protocol does not indicate that animals will be located at a holding site and transported to and from the facility several



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Correct by July 1, 2005

(b) IACUC Membership. (3) Of the members of the Committee: (ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals;

Review of IACUC records of attendance indicated that the outside member of the IACUC does not routinely attend IACUC meetings. Documented records indicated that the outside member attended in December 2002, and the IACUC secretary, a Covance employee was used in December 2003 as a substitute for the outside member. The outside member did however attend a meeting in October 2004 and in 2005. The outside member of this committee is not fulfilling the requirements of the regulations by attending meetings every other year. Substituting an employee for the outside member does not meet the requirements of the regulations. The committee should have identified this as a non compliance with federal regulations and taken actions to resolve this deficiency. A reliable outside member and possibly and alternate member should be considered.

Correct by August 1, 2005.

3.11 (a)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

(a) Cleaning of primary enclosures. When steam or water is used to clean the primary enclosure, whether by hosing, flushing, or other methods, dogs and cats must be removed, unless the enclosure is large enough to ensure the animals would not be harmed, wetted, or distressed in the process.

There were dogs in the indoor pens that were wetted during hosing of their enclosures. The small size of the enclosures makes it difficult to use a hose and clean the enclosure while keeping the dogs dry. Dogs may become distressed and hyperactive in attempts to avoid the water during the hosing of the enclosure. This may lead to an injury in an animal during the cleaning process. Dogs must be removed from the enclosure to prevent wetting during cleaning.

Correct by July 1, 2005.

3.53 (a) (1)

PRIMARY ENCLOSURES.

All primary enclosures for rabbits shall conform to the following requirements: (a) General. (1) Primary enclosures shall be structurally sound and maintained in good repair to protect the rabbits from injury, to contain them, and to keep predators out. (4) The floors of the primary enclosures shall be constructed so as to protect the rabbits' feet and legs from injury. Litter shall be provided in all primary enclosures having solid floors

There are two sections of a metal grated floor that makes up the rabbit enclosure floors. In two enclosures the sections were separated leaving a gaping space on the floor surfaces. The rabbit limbs may easily get caught in the spacing on the grated

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floor surface causing injury to the animal. The floor surface must be affixed in such a way that separation does not occur.

Correct by July 1, 2005

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(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.

The ceiling located above pen 4 in the upper holding area was warped causing the attached fluorescent light fixture to appear to be angled abnormally. The structural deficiencies with the ceiling or light fixture should be repaired to protect the animals from injury from the collapse of the light fixture and/or overhead structures.

The drain running along the back of the enclosure of lower holding area of pen 3 had a long rectangular metal grate which extended the length of the enclosure. There were several areas that had sufficient spacing to trap an animals hoof or foot causing injury. These openings in the drains must be covered to prevent animals from injuring limbs while housed in the enclosure.

Correct by July 1, 2005

3.127 (c)

FACILITIES, OUTDOOR.

(c) Drainage. A suitable method shall be provided to rapidly eliminate excess water. The method of drainage shall comply with applicable Federal, State, and local laws and regulations relating to pollution control or the protection of the environment.

The barn type housing structure for the farm animal has no drainage. The outdoor area adjacent to the barn had water accumulating from cleaning. The accumulation of water on a daily basis with any means of drainage will attract pest and odors to the area. Adequate drainage of this area is necessary to maintain a facility that complies with this regulation.

Correct by October 1, 2005

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