United States Department of Agriculture
Animal and Plant Health Inspection Service

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Inspection Report

Allergan
P.O. Box 19534
Irvine, CA 92623

Customer ID: **1168**
Certificate: **93-R-0067**
Site: 001
ALLERGAN

Type: ROUTINE INSPECTION
Date: 09-APR-2014

2.31(c)(3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The facility completed a review of their program for humane care and use of animals and the facility's animal facilities on June 7, 2013. The program review does not identify two animal welfare incidents that occurred in April and May of 2013 as significant deficiencies. According to the report submitted to the Institutional Officer (IO), no major deficiencies were found in the Animal Care and Use Program during the review.

The IACUC should submit accurate and complete reports to the IO that identifies all deficiencies found, designates them as minor or significant, and that contains a reasonable and specific plan and schedule with dates for correcting each deficiency. The IO is fully responsible for compliance with the AWA by the research facility and to ensure that any deficiencies noted can be adequately addressed.

To be corrected immediately

2.31(c)(6)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A study involving 7 rabbits was conducted on May 14, 2013, without prior IACUC review and approval. According to a facility representative, there are no records, i.e., a protocol, medical records, or results, documenting this activity.

Animal use without IACUC review and approval can result in unnecessary pain and distress for the animals. The IACUC shall review and approve all proposed activities related to the care and use of animals prior to study inception.

To be corrected immediately

2.31(c)(7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Prepared By: ALEXANDRA ANDRICOS, D V M USDA, APHIS, Animal Care **Date:** 16-APR-2014

Title: VETERINARY MEDICAL OFFICER 5038

Received by Title: FACILITY REPRESENTATIVE **Date:** 17-APR-2014

A study protocol written by study leaders was not subject to IACUC approval. Although the one study protocol that was reviewed runs under an approved blanket protocol, the procedures used in the study did not correspond with those procedures which the IACUC had reviewed and approved.

Activities involving 16 rabbits were conducted under a study protocol that had not been reviewed or approved by the IACUC. The IACUC-approved procedure for obtaining blood from rabbits is bleeding through the ear vein/ artery. According to a facility representative, the study team made a decision to perform a laparotomy on the rabbits and collect blood from the abdominal aorta. This procedure was not approved by the IACUC.

Any changes to a protocol must be reviewed and approved by the IACUC prior to conducting any activity associated with the change. An IACUC review of protocol changes is to ensure that animals do not experience unnecessary pain and distress and to verify that personnel are adequately trained to conduct the procedures to be performed.

To be corrected immediately

2.31(e)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC approved protocol involving rabbits did not contain an adequate rationale for the appropriateness of the numbers of animals to be used for that activity. The protocol stated that 60 rabbits would be used but there was no rationale provided for why these were the numbers needed to make the procedures valid.

The rationale approved by the IACUC should provide assurance that the appropriate number of animals is being used to obtain the information the activity is designed to provide. It is the responsibility of the IACUC to ensure that proposals to conduct activities in ongoing activities involving animals contain rationales that explain the appropriateness of the number of animals to be used in those activities.

To be corrected on all subsequent protocols involving covered species

2.31(e)(3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The facility IACUC only approves blanket protocols with general descriptions for all activities using animals. Study leaders subsequently write more specific, study protocols that are not seen or approved by the IACUC prior to implementation. In keeping with this policy, one study protocol that was not approved by the IACUC included a surgical procedure with inadequate anesthesia and blood collection procedures in April, 2013, that were not included in the approved protocol. Additionally, an unnecessary activity using animals took place at the facility in

May, 2013, under no protocol.

The IACUC is responsible for reviewing all aspects of animal care and use, and for evaluating protocols in order to ensure compliance with the Animal Welfare Act. In order to properly accomplish this function, the IACUC must be made aware of all procedures being conducted. It is the responsibility of the IACUC to ensure that the investigator provides a complete description of proposed activities that involve the use of animals in order that those activities may be adequately reviewed and determined to be in accordance with the Animal Welfare Act.

To be corrected by July 15, 2014

2.33(b)(1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Appropriate anesthetic equipment was not available during two procedures using regulated species.

On April 24, 2013 sixteen animals had laparotomies performed in a room dedicated for animal necropsies using injectable agents only. When some of the animals began vocalizing during the procedure an inhalant agent was placed on gauze in a nosecone which was placed over the animal's heads and the surgeries were completed with some of the animals continuing to vocalize. When it was apparent that the injectable agent was providing an insufficient plane of anesthesia the staff performing the procedures did not intubate the animals for proper inhalant anesthetic use or contact one of the facility clinical veterinarians for assistance with anesthesia.

On May 14, 2013 seven animals were used to test different injectable anesthetic routes and insufficient planes of anesthesia obtained for at least five of the animals. These procedures also took place in the same necropsy room, with no access to other drugs or anesthetic equipment that could have provided an acceptable plane of anesthesia.

Appropriate facilities, personnel, equipment, and services should be available for use during activities using animals in order to prevent unnecessary pain and distress in the animals.

Correct immediately.

2.33(b)(5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Animals were not adequately anesthetized prior to surgical procedures performed by facility employees. According to facility records, several animals exhibited signs of pain and distress during surgical procedures performed on two different dates. Laparotomies were performed on a total of 22 animals (one additional animal died prior to surgery) using inadequate anesthesia.

Prepared By: ALEXANDRA ANDRICOS, D V M USDA, APHIS, Animal Care **Date:** 16-APR-2014

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The facility should ensure that adequate anesthesia and/or analgesia is provided to animals undergoing any procedures that may cause more than slight or momentary pain or distress.

Correct immediately.

An exit briefing was conducted with the facility representatives.

Additional Inspectors

Rosendale Marcy, Veterinary Medical Officer

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United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1168
Inspection Date: 09-APR-14

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1168	93-R-0067	001	ALLERGAN	09-APR-14

No Animals were Inspected.

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	