



Allergan, Inc.  
2525 Dupont Drive  
Irvine, CA 92612

### **CITATION AND NOTIFICATION OF PENALTY**

We believe that you violated the Animal Welfare Act (7 U.S.C. § 2131 et seq.) (AWA), as described below.

While Allergan, Inc.'s payment of the Settlement Agreement constitutes a waiver of their right to a hearing, Allergan, Inc. neither admits nor denies that the said matters either took place or constitute a violation of any laws.

#### **Date of Violation: April 24, 2013**

##### **9 C.F.R. § 2.31 Institutional Animal Care and Use Committee.**

(c) IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(7) Review and approve, require modification in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

(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.

(4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals.

The IACUC failed to review and approve modifications to a protocol using 16 rabbits. The IACUC approved the broad protocol, #789-100100-2012, which called for blood collection through the ear vein or artery, but failed to review and approve the related study protocol, #IS13004, which involved blood collection through the abdominal aorta. Protocol #789-100100-2012 did not include a complete description of the proposed use of the animals or include information concerning how animal discomfort would be limited to that which was unavoidable for the research. The study protocol, #IS13004, did not include provisions to assure that the appropriate drugs were used to minimize discomfort and pain to the rabbits used in the study. Allergan performed the protocol on 16 rabbits without properly anesthetizing them. At least three of the rabbits vocalized during the procedure and others displayed movement, pain and distress.

**Date of Violation: On or about April 2013 – May 2013**

**9 C.F.R. § 2.32(b) Personnel qualifications.**

Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under this section and § 2.31.

Allergan failed to train and review personnel qualifications with sufficient frequency to fulfill Allergan's responsibilities under sections 2.31 and 2.32 of the Animal Welfare Act regulations. Allergan personnel carried out protocols without IACUC review and approval, and failed to provide proper care to animals used in procedures. Although several employees were involved in April and May 2013 procedures where there were deficiencies in animal care and treatment, they were unwilling or unaware of their reporting responsibilities.

**Date of Violation: April 24, 2013**

**9 C.F.R. § 2.33(b) Attending veterinarian and adequate veterinary care.**

Each research facility shall establish programs of adequate veterinary care that include:

The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter.

Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

Allergan failed to administer adequate anesthesia to 16 rabbits prior to an unapproved study protocol (#IS13004) involving the collection of blood from the abdominal aorta through an abdominal incision. The rabbits experienced more than momentary pain and distress during the procedure and at least three of the rabbits vocalized before receiving additional anesthesia. Difficulties in administering the additional anesthesia, exacerbated by performing the protocol in a necropsy room that did not have additional drugs, oxygen or anesthesia equipment available, caused the rabbits to experience further unnecessary suffering. Personnel provided additional anesthesia using an inhalant agent with gauze and a nosecone after determining that they had not adequately anesthetized the rabbits with what was later determined to be a leftover anesthesia cocktail intended for dogs.

**Date of Violation: May 14, 2013**

**9 C.F.R. § 2.31(c)(6) IACUC functions.**

With respect to activities involving animals, the IACUC, as an agent of the research facility shall: Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals...

The IACUC failed to review and approve a study to test injectable anesthetics using seven rabbits. One rabbit died immediately after

receiving the anesthesia intravenously rather than intramuscularly, and additional animals showed signs of pain. Allergan failed to develop and document a protocol, have the IACUC review a protocol, or give the study a protocol number.

**Date of Violation: May 14, 2013**

**9 C.F.R. § 2.33(b)** Attending veterinarian and adequate veterinary care. Each research facility shall establish and maintain programs of adequate veterinary care that include:

The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter.

Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

Allergan conducted an unapproved, unnumbered study of injectable anesthetics using seven rabbits in a necropsy room that did not have additional drugs, oxygen or anesthesia equipment available. Personnel did not adequately anesthetize the rabbits. One rabbit died when personnel administered the anesthesia intravenously rather than intramuscularly, and additional animals showed signs of pain.

**Date of Violation: April 9, 2014**

**9 C.F.R. § 2.31(c)(3)** IACUC functions.

With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Officer of the research facility...The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A – Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals...

The IACUC failed to disclose the 4/23/13 and 5/14/13 animal welfare incidents in its 6/7/13 report to the Institutional Officer as significant deficiencies.

The penalty for the alleged violation(s) described above is \$31,775.