



INSPECTION REPORT

**SCHERING-PLOUGH ANIMAL
HEALTH, CORP**

**P O BOX 3113
OMAHA, NE 68103**

Customer ID: 1550

Certificate: 47-R-0010

Site: 001

**SCHERING-PLOUGH ANIMAL
HEALTH**

Inspection

Type: ROUTINE INSPECTION

Date: JUN-30-2006

2.31 (d) (1) (iv)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing.... Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements....

...(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will:

(A) 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...

Currently protocols are not assigned a pain category until after the activity is completed. This does not provide the IACUC with the necessary advance information to determine that the activities will be conducted in accordance with the animal welfare standards and regulations. For instance, if a protocol is submitted under "Category E" (... research, surgery, or tests that will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affected the procedures, results, or interpretation of the...research,...surgery, or tests), the IACUC would expect a full written justification to be included in the research proposal. The IACUC could then properly review the proposal and make a fully informed decision to approve or disapprove the activity.

Protocols with IACUC do not properly address the alleviation of pain/distress. Further, the principal investigator has not justified IN WRITING why withholding appropriate sedatives, analgesics, and/or anesthetics is scientifically justified. Protocol does state that animals will be considered moribund and will be euthanized when they become "severely depressed, dehydrated, show signs of inappetance, and/or are unable to move", however, a less serious gradation of clinical signs can/does occur in the animals prior to them becoming moribund. The principal investigator, therefore, should address how these lesser symptoms could be treated medically, or provide a full written explanation as to why treatment should be withheld. All protocols should include this information.

(Correction timeline for this item: Correct by August 30, 2006)

Prepared By:

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