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INSPECTION REPORT

**JOHNSON & JOHNSON
PHARMACEUTICAL R&D LLC**

**Customer ID: 33183
Certificate: 22-R-0138**

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**Site: 002
JOHNSON & JOHNSON PHARM**

**Inspection
Type: ROUTINE INSPECTION
Date: SEP-26-2005**

2.31 (d) (1) (iv) (A) DIRECT

2.31 (e)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(iv)(A) IACUC: Procedures that may cause more than momentary or slight pain or distress to the animals will 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.

Animal proposal (b)(4) This proposal was approved by the IACUC as having an unrelieved painful/distressful procedure, but the principal investigator did not provide written scientific justification for not relieving the pain/distress. The principal investigator also did not include the anesthetics used for the terminal blood sample and the route of the euthanasia agent.

The IACUC must ensure that the principal investigators provide written scientific justification for not relieving pain/distress to ensure that pain and distress to animals is minimized and will continue only to the necessary period of time. Also the IACUC must ensure that principal investigators use appropriate sedatives, analgesics or anesthetics for the relieved painful/distressful procedures.

The principal investigator for the above proposal must provide the required written scientific justification for not relieving the pain/distress and provide the necessary information for the pain/distress that can be relieved.
Correct by November 1, 2005.

Section 2.31(e) IACUC: A proposal to conduct an 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;
- (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; and)
- (5) A description of any euthanasia method to be used.

(1) Animal proposal (b)(4) In room D-136 the cage cards for dog 544213 and dog 544175 indicated that these dogs were on animal proposal (b)(4) which involves a terminal procedure. However, these dogs had a major survival procedure performed on 9-14-05. There was no indication of the proposal number in the dogs' medical records that included

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the surgery and post-op records. During the inspection the APHIS official was finally informed that the dogs were now on proposal (b)(4). Proposal (b)(4) was approved for 20 dogs. The facility's tracking system for the animals still indicated that 20 dogs could be ordered for proposal (b)(4). However, at least 8 dogs have had the major survival procedure for the proposal and none of the dogs had the correct proposal number on their cage card or in their medical records. These dogs were not included in the facility's tracking system for the proposal. During the inspection the cage cards for the dogs were corrected and the facility's tracking system updated to include the 8 dogs on proposal (b)(4).

For proposal (b)(4) there is no indication of the size of the observation chamber that the animals will be kept during the test procedure. The description of the analgesics and antibiotic administration in proposal differ from what was documented in the records for all eight dogs. The dogs' records do not include the medications and observations/assessments made over the weekend (9/17/05-9/18/05 and/or 9/24/05-9/25/05).

The animal proposals must include a complete description of the proposed use of the animals. Animal proposals need to be followed or amended. Proposal (b)(4) needs to include all the appropriate information and be followed as it was approved by the IACUC. Documentation pertaining to the observations and care given to the animals as described in the proposals need to be maintained on weekend and holidays, not just normal business days. The facility's records should accurately reflect which animals are on what proposal.
Correct by November 1, 2005.

(2) Animal proposal (b)(4) The rationale for the number of animals requested for animal proposal (b)(4) just explains why a statistical assessment of sample size can not be done. There is no explanation for how the number of animals was determined. The principal investigator must provide a rationale for the appropriateness of the number of animals to be used.
Correct by November 1, 2005.

(3) Animal proposal (b)(4) The proposal indicates that animals will be used for staff training but there is no description of how the animals will be used for the training. The proposal also does not describe the subcutaneous or intramuscular dosing. The proposal also indicates that the dosage levels will cause no pain or distress, but includes agents to provide relief to three potentially painful/distressful responses.

The principal investigator must provide a complete and consistent description for the use of the animals. If animals have experienced pain/distress then pain/distress issues must be addressed in the proposal.
Correct by November 1, 2005.

(4) Animal proposal (b)(4) This proposal was approved by the IACUC as having a relieved painful procedure. From the proposal's description the animals appear to be under continuous anesthesia. However, information obtained from one of the protocol associates indicated that the animals are only under anesthesia for the initial injection of the irritant and then allowed to regain consciousness. The animals would be expected to experience more than momentary and slight pain or distress from the procedure. Also the proposal states that both rear paws may be used for the (b)(4) with no justification. The protocol associate did indicate that only one paw is used for the testing.

The principal investigator must follow or amend this proposal. Pain and distress issues must be addressed as specified in the regulations.
Correct by October 3, 2005.

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2.33 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b)(3) Veterinary care: Each research facility shall establish and maintain programs of adequate veterinary care that include daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

In room D210 one guinea pig was observed with a rough hair coat and numerous scabs on its lower back/rear end. During the inspection this guinea pig was put in a separate enclosure and brought to the attention of the veterinarian. Corrected during the inspection.

3.31 (b)

SANITATION.

Section 3.31(b) Housekeeping: Premises shall be kept clean to facilitate the prescribed husbandry practices set forth in this subpart.

The two air filters for the guinea pig room D210 (last changed on 9/06/05) and for the hamster room 207 (last changed on 9/07/05) were excessively dirty/dusty. The air filters need to be cleaned or changed on a more frequent basis. Corrected during the inspection.

3.84 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

Section 3.84(c) Housekeeping: Premises shall be kept clean to facilitate the husbandry practices set forth in this subpart.

In the animal procedure room D-131 there were stored four primate chairs spotted with a dark colored substance and/or fecal material. The chairs need to be kept clean to ensure the health of the animals and to minimize contamination between animals.

Corrected during the inspection.

Note: Discussed the new environmental enhancement plan that is being developed.

This inspection was conducted on September 26, 2005 and September 29, 2005.

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