



**INSPECTION REPORT**

SEP 23 2006

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

**Customer ID: 33183**

**Certificate: 22-R-0138**

**Site: 002**

**JOHNSON & JOHNSON PHARM  
R&D**

**Inspection  
Type: ROUTINE INSPECTION**

**Date: SEP-19-2006**

**P O BOX 300 ROUTE 202 SOUTH  
RARITAN, NJ 08869**

**2.31 ( d ) ( 1 ) ( iv ) ( A )**

**2.31 ( e ) ( 2 )**

**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 activity proposal (b)(4) was approved by the IACUC as a proposal that could result in unrelieved animal pain and distress, USDA category E on the annual report. The principal investigator only stated that anesthetics, analgesics or tranquilizer drugs may alter/invalidate the study results (question 9, page 11). There was no scientific justification provided for this statement. Also the investigator answered N/A when asked to list applicable humane endpoints (question 23, page 13) and this is not appropriate for proposals that may cause animals pain/distress.

Animal activity proposal (b)(4) was just approved by the IACUC as a proposal that could have animals in unrelieved pain and distress, USDA category E on the annual report. The principal investigator refers to the expired proposals for the management of the animals but did not provide scientific justification for not relieving the animal pain/distress when the proposal is expired and the animals are transferred to proposal (b)(4) (page 1).

The IACUC is responsible for ensuring that 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. This is necessary to ensure the health and well-being of the animals.  
Correct by October 20, 2006.

Section 2.31(e)(2) IACUC: A proposal to conduct an activity involving animals must contain a rationale for the appropriateness of the species of animal to be used.

Animal activity proposal (b)(4) does not explain why guinea pigs are needed in addition to the rats and mice. The rationale for the use of the guinea pigs is the same as for the other rodents and needs to include the rationale for the addition of the guinea pigs to ensure that the appropriate species are used.  
Correct by October 20, 2006.

**Prepared By:** Mary Geib  
MARY GEIB, D V M , USDA, APHIS, Animal Care

**Date:**  
SEP-20-2006

**Title:** VETERINARY MEDICAL OFFICER . Inspector ID: 1021

**Received By:** \_\_\_\_\_  
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**Date:**  
SEP-20-2006



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Section 2.31(e) IACUC: A proposal to conduct an 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.

Animal activity proposal (b)(4) includes a survival surgery and blood collection. The proposal states that the surgeries will be done on Monday only (question 6, page 9), but the surgeries were performed on Tuesday, September 19, 2006. The use of (b)(4) during and after surgery is described (question 8, page 9), but a (b)(4) was used instead after surgery. (b)(4) was to be given post-operatively once daily for three days for pain control (question 19, page 11), but the surgeon stated during this inspection that (b)(4) was not started until the morning after the surgery, September 20, 2006. Also (b)(4) not every 24 hours. A veterinarian for the facility was present during the inspection and acknowledged that the dosing interval for (b)(4) was more frequent than every 24 hours and should have started the day of the surgery. After surgery the animals were to be housed individually (question 14, page 10), but were housed three per enclosure. The proposal stated that documentation will be kept for the surgical procedures (page 2), but the surgeon did not have records. Blood collection was described once at the time of euthanasia, but the proposal lists nine sites (question 12, page 9) with no explanation for the number of sites or justification for the potentially painful sites.

Animal proposals must include a complete description of the proposed use of the animals with appropriate analgesic dosing/monitoring frequency to maintain the health and well-being of the animals. Animal proposals need to be followed or amended. Animal proposal (b)(4) needs to include all the appropriate information and be followed as approved by the IACUC. Documentation pertaining to the observations and care given to the animals as described in the proposals need to be maintained.

Correct prior to performing more surgeries.

**2.32**

**DIRECT**

**PERSONNEL QUALIFICATIONS.**

Section 2.32 Personnel qualification:

- (a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.
- (b) 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 Sec. 2.31.
- (c) Training and instruction of personnel must include guidance in at least the following areas:
  - (1) Humane methods of animal maintenance and experimentation, including:
    - (i) The basic needs of each species of animal;
    - (ii) Proper handling and care for the various species of animals used by the facility;
    - (iii) Proper pre-procedural and post-procedural care of animals; and
    - (iv) Aseptic surgical methods and procedures

The investigator/surgeon for animal proposal (b)(4) did not follow the IACUC approved proposal, did not administer the (b)(4) analgesic until the day after the surgery, did not notify the veterinarian about the abnormal hamster and did not know of the documentation requirements for animal surgery. The facility is responsible for ensuring that all personnel are appropriately trained and qualified to perform their duties. This is necessary to ensure the health and well-being of the animals. Correct prior to additional animal work.

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(b)(6), (b)(7)c

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Title:

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**INSPECTION REPORT**

SEP 25 2006

**2.33 ( b ) ( 3 )**

**DIRECT**

**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

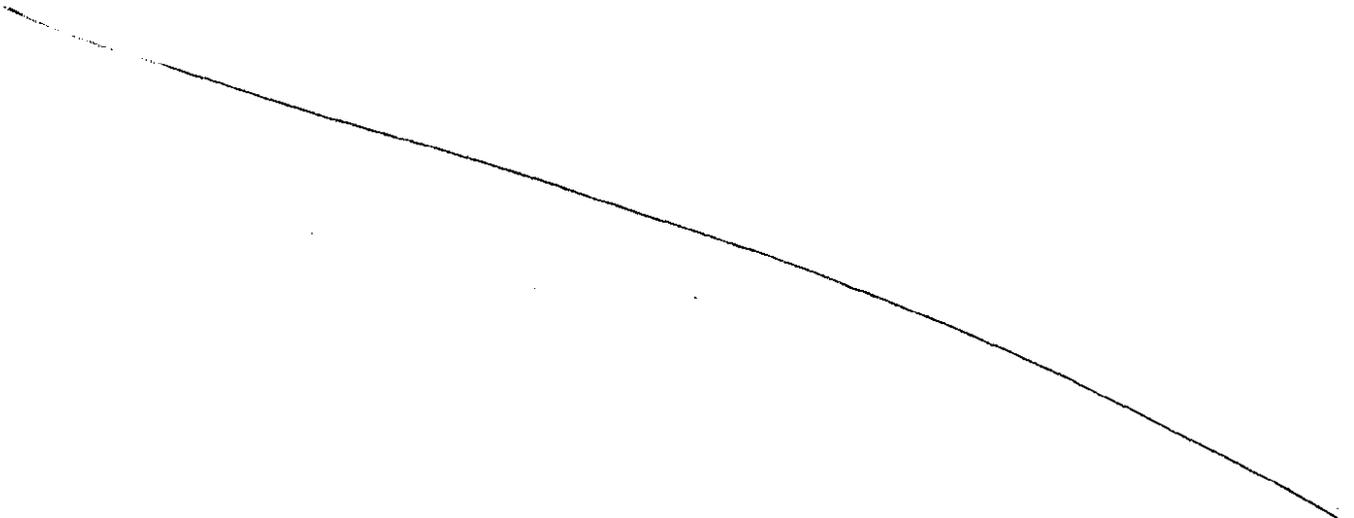
Section 2.33(b)(3) Veterinary care: Each research facility shall establish and maintain programs of adequate veterinary care that include daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than 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.

(1) Dogs in rooms 133 and 136 had excessively long nails. Excessively long nails may break off and bleed or get caught in the enclosure causing the animal discomfort. The nails were trimmed during the inspection.  
Corrected during the inspection.

(2) Six hamsters on proposal (b)(4) did not receive their (b)(4) for analgesia until the day after their surgery. This is not considered appropriate post-operative care and the animals were expected to receive the (b)(4) on the day of the surgery to relieve the post-operative pain.  
Correct for future surgeries.

(3) One hamster on proposal (b)(4) was not acting normal on the day following surgery: hunched position and moved slowly with shaking motions. This investigator did not document the abnormality or notify the veterinarian. The veterinarian examined and treated the animal during the inspection.  
Corrected during the inspection.

This inspection was conducted on September 19, 2006 and September 20, 2006.



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