



APR 10 2006

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**INSPECTION REPORT**

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

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

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

**Site: 002  
JOHNSON & JOHNSON PHARM  
R&D  
Inspection  
Type: ROUTINE INSPECTION  
Date: APR-04-2006**

- 2.31 ( c ) ( 3 )
- 2.31 ( d ) ( 1 ) ( iv ) ( A )
- 2.31 ( d ) ( 2 )
- 2.31 ( e ) ( 1 )
- 2.31 ( e ) ( 4 )

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

Section 2.31(c)(3) IACUC: The IACUC report to the Institutional Official must contain a reasonable plan and schedule for correcting each deficiency noted in the program or facility inspection.

The IACUC report for October of 2005 did not have a plan for correction of all of the minor deficiencies noted during the facility inspection. All deficiencies noted during the program or facility inspection must have a plan for correction to comply with the Animal Welfare regulations and to keep the Institutional Official informed.  
Correct for the next IACUC report to the Institutional Official.

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 relieving animal pain and distress, USDA category D on the annual report. The investigator indicated in several areas that the proposal was a category D, however, the principal investigator indicated that no pain/distress relieving agents would be used (question 7) and answered N/A when asked to list applicable humane endpoints (question 23).

Animal activity proposals must clearly indicate if animal pain and distress will or will not be relieved. The proposal must be consistent and not contradictory. 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.  
Correct by May 5, 2006.

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

Date:  
APR-04-2006

Title: VETERINARY MEDICAL OFFICER (Inspector ID: 1021)

Received By: [Redacted]

Date:  
APR-04-2006

Title: [Redacted]



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Section 2.31(d)(2) IACUC: No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.

A proposal associate participated in the review of the following animal activity proposals (b)(4)  
(b)(4) Proposal associates may not participate in the IACUC review and approval process of their animal activity proposals. This is a conflict of interest.  
Correct from this day forward.

Section 2.31(e)(1) IACUC: A proposal to conduct an activity involving animals must contain the approximate number of animals to be used.

Animal activity proposal (b)(4) was approved by the IACUC for 30 animals. During this inspection there were 45 animals assigned to this proposal, 17 of these animals were just transferred to this proposal. Principal investigators must not exceed the number of animals approved for their proposals. Proposals must be followed as approved by the IACUC. Amendments to proposals must receive IACUC approval prior to being implemented.  
Correct from this day forward.

Section 2.31(e)(4) IACUC: A proposal to conduct an activity involving animals must contain 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) stated that pharmaceutical grade (b)(4) would be used for anesthesia for the terminal procedure for guinea pigs. However an investigator used chemical grade (b)(4). Investigators must follow their animal activity proposals as approved by the IACUC to ensure the health and well-being of the animals.  
Correct from this day forward.

**2.33 ( b ) ( 1 )**

**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

Section 2.33(b)(1) 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 this subchapter.

An investigator for animal activity proposal (b)(4) used chemical grade instead of pharmaceutical grade (b)(4) for anesthesia for terminal procedures in guinea pigs. The proposal did not include using a chemical grade compound or provide justification for its use. Investigators are expected to use pharmaceutical grade medications whenever they are available, even in acute procedures. Non-pharmaceutical grade chemical compounds should only be used in regulated animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical grade product.  
Correct from this day forward.

Note: This inspection was conducted on April 3, 2006 and April 4, 2006.

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

Date:  
APR-04-2006

Title: VETERINARY MEDICAL OFFICER Inspector ID: 1021

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