



INSPECTION REPORT

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JOHNSON & JOHNSON
PHARMACEUTICAL R&D LLC

Customer ID: 33183
Certificate: 22-R-013E

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Site: 002
JOHNSON & JOHNSON PHARM
R&D
Inspection
Type: ROUTINE INSPECTION
Date: OCT-30-2006

2.33 (b) (2) DIRECT
ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b)(2) Veterinary care: Each research facility shall establish and maintain programs of adequate veterinary care that include the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend and holiday care.

Animal #2 on animal activity proposal (b)(4) was noted to be dehydrated and received fluid therapy on September 20-24, 2006; on September 27, 2006; and September 29, 2006 with the study ending on September 30, 2006. There is no indication or documentation of the hydration status or fluid therapy for animal #2 on September 25-26, 2006 and September 28, 2006.

Animal #3 on animal activity proposal (b)(4) was noted to be dehydrated and received fluid therapy on September 20-24, 2006; on September 27, 2006; and died on September 29, 2006. There is no indication or documentation of the hydration status or fluid therapy for animal #3 on September 25-26, 2006 and September 28, 2006.

Proposal (b)(4) describes the monitoring of the animals for 5 days after surgery then once weekly thereafter. However, animals that are observed with abnormalities and/or being treated for medical conditions are expected to continue with the appropriate care to maintain their health and well-being. Animals #2 and #3 should have had appropriate care reflected in the records for September 25-26, 2006 and September 28, 2006.

Animals #7 and #8 on Proposal (b)(4) were to receive (b)(4) after surgery. (b)(4) has a dosing interval of (b)(4). The animals received their (b)(4) on the day of surgery and did not receive their (b)(4) until (b)(4). Animal #8 was noted as less active than animal #7 and no evidence of eating, drinking or feces. The (b)(4) Analgesics must be given at appropriate frequencies to ensure adequate pain relief for the animals.

Animal #8 was observed to be abnormal by the investigator after normal business hours and sent the veterinarian an E-mail. The veterinary staff was gone for the day and did not receive the message. The animal was found dead the following morning. The research facility is responsible for ensuring that investigators can inform the veterinary staff about abnormal animals in a timely manner so they can receive adequate veterinary care.

The research facility must establish and maintain programs of adequate veterinary care that include the appropriate daily care and documentation of animal being treated for medical abnormalities, the appropriate administration of analgesics based on their dosing frequency, and the availability of adequate veterinary care after normal business hours.

Correct from this day forward.

Prepared By: Mary Geib
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Title: VETERINARY MEDICAL OFFICER, Inspector ID: 1021
(b)(6), (b)(7)c

Date:
OCT-30-2006

Received By: _____
Title: _____

Date:
OCT-30-2006