



INSPECTION REPORT

OCT 10 2006

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204629 insp_id
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BIOQUAL INC

Customer ID: 93

Certificate: 51-R-0036

Site: 001

BIOQUAL

Inspection

Type: ROUTINE INSPECTION

Date: SEP-22-2006

**9600 MEDICAL CENTER DRIVE
ROCKVILLE, MD 20850**

2.31 (e)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

- (1) Identification of the species and the approximate number of animals to be used;
- (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.

***In the review of various protocols, it was noted that there are inconsistencies among prptocols in areas of justifications, pain and distress categories, and defining of endpoints. For Example: (b)(4) states the potential to see morbidity in the animals. However, the pain and distress category is indicated as a Catagory 1 (USDA Catagory C). (b)(4) states "animals that progress to terminal dsease will be euthanized." However, "morbidity" and terminal disease" are not clearly defined. The 2005 USDA inspection revealed that (b)(4) was amended to reflect a change in species of primate but a justification of the change was not indicated. Discussions with IACUC members and staff revealed everyone has a clear understanding of what is expected on each study and why it is being conducted. However, within the increase number of protocols for review and no designated IACUC Coordinator, written details are being overlooked. A system must be established or a person designated to ensure accuaracy of the protocols prior to approval. Correct by October 31, 2006.

This was a focused inspection of the MC and P facilities, animals, and enrichment.

Prepared By: Gloria A. McFadden
GLORIA MCFADDEN, D V M , USDA, APHIS, Animal Care

Title: **VETERINARY MEDICAL OFFICER** Inspector ID: 1048

Date:
SEP-22-2006

Received By: (b)(6), (b)(7)c

Title: (b)(6), (b)(7)c

Date:
SEP-22-2006