



INSPECTION REPORT

1832 cust_id
233279 insp_id
1463 site_id

AGBIO COMPANY

Customer ID: 1832
Certificate: 93-R-0412

1513 RIVER OAKS DRIVE
MODESTO, CA 95356

Site: 001
AGBIO COMPANY

Inspection
Type: ROUTINE INSPECTION
Date: JUL-27-2006

2.31 (c)(7) DIRECT

2.31 (e)(2) REPEAT NCI

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC)

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

Two significant changes to ongoing activities were not approved by the Institutional Animal Care and Use Committee (IACUC). The IACUC approved protocols at the facility provide guidelines for the collection of blood from rabbits.

1) One protocol establishes a schedule for blood collection and quantifies the amount of blood to be collected from rabbits at each bleeding. According to the protocol, a set amount of blood is to be collected once every other week. According to production records, the rabbits were being bled at two to three day intervals, with half of the quantity specified in the protocol being drawn at each two to three day interval. Subsequent bleedings were performed at approximately two week intervals. While the total amount of blood being obtained under this modified schedule was approximately equal to the schedule set forth in the protocol, the change was made without the written approval of the IACUC and attending veterinarian. Significant changes in procedures could be detrimental to the health and wellbeing of the animals, thus these changes should be reviewed and approved by the IACUC prior to their implementation.

2) Twice the approved amount of blood was harvested from rabbit number Z31429 between June 24 and July 1, 2006, and again from July 15 and July 22, 2006 for a total of eight procedures. The extra procedures were said to be necessary due to the death of a second rabbit that had been immunized with the same antigen but died prior to collection. The collection of excessive amounts of blood could be detrimental to the health and wellbeing of the animals. A system should be in place to ensure that the quantity of blood collected does not exceed the amount approved by the IACUC.

Correct the first item by August 17, 2006.
Correct the second item immediately.

Prepared By: [Signature]
MARCY ROSENDALE, V.M.O., USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector ID: 5039

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JUL-31-2006

Received By: _____

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Date:

Title:

AUG-02-2006



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- (e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing 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.

Both IACUC approved protocols provided inadequate rationales for the appropriateness of the numbers of rabbits being used for that activity. Justification for the number of animals to be used is important in order to ensure that the minimum number of animals is used for activities described in the protocols. It is the responsibility of the IACUC to ensure that proposals to conduct activities as well as proposed significant changes in ongoing activities involving animals contain rationales that explain the appropriateness of the species and numbers of animals to be used in those activities.

Original correction date: February 27, 2006.

Note: Previously identified non-compliant items 2.31 (d) (1) (ii), 2.31 (e) (1), and 2.31 (e) (3) had been corrected at the time of the inspection.

Prepared By: *Marcy Rosendale* DVM, VMD
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AUG - 7 2006

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Date:
AUG-02-2006