



INSPECTION REPORT

1832 cust_id
233216 insp_id
1463 site_id

AGBIO COMPANY

Customer ID: 1832

Certificate: 93-R-0412

Site: 001

AGBIO COMPANY

1513 RIVER OAKS DRIVE
MODESTO, CA 95356

Inspection

Type: ROUTINE INSPECTION

Date: DEC-01-2005

2.31 (d) (1) (ii)

2.31 (e) (1)

2.31 (e) (2) REPEAT NCI

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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

(d) IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available.

One IACUC (Institutional Animal Care and Use Committee) approved protocol describes procedures that may be expected to cause more than momentary or slight pain or distress in the animals to which the procedures are being applied. The protocol does not include a written narrative description of the methods and sources consulted, including the date the search was performed, the period covered by the search and the key words and/or search strategy used, when considering alternatives to these procedures.

The IACUC is responsible for ensuring that the investigator has made a reasonable and good faith effort to determine the availability of alternative procedures. If the literature search identifies an alternative method or methods, the written narrative should justify why any alternatives were not suitable. The IACUC should ensure that approved protocols contain a written narrative description of the methods used and sources consulted to determine the availability of alternative procedures.

Correct by February 27, 2006.

Prepared By: Marcy Rosendale, DVM, VMD
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Title: VETERINARY MEDICAL OFFICER , Inspector ID: 5039

Date:
DEC-02-2005

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Title:

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DEC-29-2005

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

(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:

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

One IACUC (Institutional Animal Care and Use Committee) approved protocol for the production of antibodies using rabbits authorizes the use of approximately 3000 rabbits per year for this activity. At the time of the inspection, approximately 300 rabbits had been used under this antibody production protocol. It is the responsibility of the IACUC to ensure that significant changes to all ongoing activities involving animals contain an accurate representation of the approximate number of animals to be used for that activity.

Correct by February 27, 2006.

(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.

One IACUC approved protocol provided an inadequate rationale for the appropriateness of the numbers of rabbits being used for that activity. A second protocol contained no rationale for the appropriateness of animals to be used.

Justification for the number of animals to be used is important in order to ensure that the minimum number of animals are used for activities described in the protocols. It is the responsibility of the IACUC to ensure that all proposals to conduct activities as well as proposed significant changes in ongoing activities involving animals contain rationales that explain the appropriateness of the numbers of animals to be used in those activities.

Correct by February 27, 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:

(3) A complete description of the proposed use of the animals.

One IACUC approved protocol calls for the euthanasia of rabbits to be followed by the harvest of the spleens and popliteal lymph nodes. As written, this protocol implies that all the rabbits are subject to euthanasia and organ harvesting. Instead, only a portion of the rabbits are subject to euthanasia. Additionally, this protocol does not describe how the rabbits are selected for euthanasia and organ harvesting verses blood collection.

It is the responsibility of the IACUC to ensure that all protocols provide a complete description of proposed activities that involve the use of animals in order that those activities may be reviewed prior to their approval.

Correct by February 27, 2006.

Note:

The previously identified non-compliant items were corrected at the time of the inspection;

2.33 (b)(2) of the November 22, 2004 inspection

2.33 (b)(4) of the August 24, 2004 inspection

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