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INSPECTION REPORT

**SOUTHERN BIOTECHNOLOGY
ASSOC., INC.**

Customer ID: 835
Certificate: 64-R-0018

P.O. BOX 26221
BIRMINGHAM, AL 35260

Site: 001
SOUTHERN BIOTECHNOLOGY

Inspection
Type: ROUTINE INSPECTION
Date: APR-25-2007

- 2.31 (a) REPEAT NCI
- 2.31 (d) (1) (ii) REPEAT NCI
- 2.31 (d) (1) (iii) REPEAT NCI
- 2.31 (e) (2) REPEAT NCI

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(a) The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility's animal program, facilities, and procedures.

***The IACUC committee is composed of five members. Discussion with two of the members and documentation/or lack of documentation reviewed today and in past inspections indicate that training in IACUC functions is necessary.

The following noncompliance's in IACUC function documented on previous inspections (08/22/06, 06/01/06 and 06/05/05) have not been corrected (i.e. the protocols do not provide the information that is required in Sections 2.31 (d) and (e), for example; written assurances that the research is not unnecessarily duplicative, a search for alternatives, and justification of numbers and rationale for species requested. Clarification of the Roles and responsibilities of the IACUC and IACUC function is necessary. I have discussed the need for further training with the IACUC Chairperson (recently replaced), the Institution Official and Facility Manager. I have provided information on formal training courses and seminars occurring locally and nationally and I have provided information on some of the websites that contain information for IACUC's that can assist them in meeting their training needs.

(d)(1)(ii) The IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that 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.

***The antibody producing protocols use Complete Freund's adjuvant for the initial injection. The IACUC revised the protocols in September of 2006, but there is no documentation or written narrative indicating the facility has considered alternatives to this potentially painful procedure included in the protocol provided for review during this inspection. A written narrative describing the methods and sources used to determine no alternatives were available must be included on the protocol.

Prepared By: Michelle B. Williams DVM
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(Section 2.31 continued)

(d)(1)(iii) The IACUC shall determine that the following requirements are being met: principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments.

***The antibody production protocols do not contain a written assurance that the procedures are not unnecessarily duplicative.

A written assurance that the research is not unnecessarily duplicative must be included in the protocols.

(e)(2) A proposal to conduct an activity involving animals or to make a significant change in an ongoing activity involving animals must provide a rationale for involving animals and for the appropriateness of the species and numbers of animals to be used.

***There is no rationale provided in the protocols for involving animals and for the appropriateness of the species and numbers of animals to be used. IACUC minutes indicate this noncompliance was discussed at the last IACUC meeting in September 2006 at which time the protocols were revised but no statement was added to the protocol. A statement containing the rationale for using animals, the appropriateness of the species and the numbers used must be provided in the protocol.

2.32 (a)

PERSONNEL QUALIFICATIONS.

This item was previously cited on last inspection but has not reached its correction date.

(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel as required in Section 2.32 (b).

***Two of the three employees at the farm have recently been replaced. The Vivarium Manager has been employed for three months and has full responsibility at the farm. The animal caretaker has been employed at the facility for less than three months and is required to handle the animals. There is no documentation indicating these employees have been trained to perform their duties.

Documentation of previous experience, training provided at the facility, and any previous training applicable to their position must be maintained and updated as necessary. It shall be made available for review during inspection. Correct by May 15, 2007.

This inspection conducted as a focused inspection for follow-up on noncompliances cited on last inspection (3/13/07).

There has been much improvement since the last inspection. The following noncompliances previously cited have been corrected: Section 2.33(b)(2), Section 3.57, Section 3.125(d) and Section 3.132

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