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Inspection Report

CALVERT LABORATORIES INC.

Customer ID: 366

Certificate: 23-R-0107

Site: 001

SCOTT TECHNOLOGY PARK

Type: ROUTINE INSPECTION

SCOTT TECHNOLOGY PARK

130 DISCOVERY DRIVE

Date: Nov-02-2009

SCOTT TOWNSHIP, PA 18447

3.8

EXERCISE FOR DOGS.

Section 3.8: Exercise for dogs: Research facilities must develop, document and follow an appropriate plan to provide dogs with the opportunity for exercise.

In room T-V there are 20 dogs housed in enclosures that require the facility to provide the dogs with the opportunity for exercise. The plan for the facility to provide these dogs with exercise states that the dogs will be given the opportunity for exercise three times a week. The last time these 20 dogs were given the opportunity for exercise was one week ago on October 26, 2009. The facility must follow its plan to provide dogs the opportunity for exercise to maintain the well-being of the dogs and to comply with the Animal Welfare standards. Correct by November 3, 2009.

Prepared By:

MARY E GEIB, D V M

USDA, APHIS, Animal Care

Date:

Title:

VETERINARY MEDICAL OFFICER Inspector 1021

Nov-02-2009

Received By:

(b)(6),(b)(7)(c)

Date:

Title:

Nov-02-2009

Inspection Report

CALVERT LABORATORIES INC Customer ID: 366

Certificate: 23-R-0107

SCOTT TECHNOLOGY PARK Site: 001

100 DISCOVERY DRIVE SCOTT TECHNOLOGY PARK

Type: ROUTINE INSPECTION

OLYPHANT, PA 18447 Date: Mar-11-2009

No non-compliances identified this inspection.

Prepared By:

MARY E GEIB, D V M

USDA, APHIS, Animal Care

Title:

VETERINARY MEDICAL OFFICER Inspector 1021

Mar-11-2009

Received By:

(b)(6),(b)(7)(c)

Title:

Date:

Date:

Mar-11-2009

маев 293448 insp_id

Inspection Report

CALVERT LABORATORIES INC.

Customer ID: 366

Certificate: 23-R-0107

Site: 001

SCOTT TECHNOLOGY PARK

SCOTT TECHNOLOGY PARK

Type: ROUTINE INSPECTION

Date: Jun-18-2008

SCOTT TOWNSHIP, PA 18447

2.36 (b)

ANNUAL REPORT.

Section 2.36(b) Annual report: The annual report shall:

- (5) State the common names and the numbers of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. Routine procedures (e.g., injections, tattooing, blood sampling) should be reported with this group;
- (6) State the common names and the numbers of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used;
- (7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report;
- (8) State the common names and the numbers of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.

The facility's 2007 Annual Report for number of animals used did not correspond with the numbers on the spread sheet shown during this inspection. More animals were used during the reporting period than were documented on the Annual Report. The explanation given was that not all the study directors had responded with their animal disposition forms in time for the 2007 Annual Report so their animals were not reported. The research facility is responsible for reporting all the animals used during the reporting period.

The annual reports from research facilities must be accurate to comply with the Animal Welfare regulations and for data based on annual reports to be a valid assessment of animal use in research. Correct for future Annual Reports.

Prepared By:			
	MARY E GEIB, D V M	USDA, APHIS, Animal Care	Date:
Title:	VETERINARY MEDICAL OFFI	Jun-18-2008	
Received By:	(b)(6),(b)(7)(c)		Date:
Title:			Jun-18-2008

Page 1 of 2



маев 293448 insp id

Inspection Report

2.36 (b)

ANNUAL REPORT.

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- (7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report;
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Prepared By:			
	MARY E GEIB, D V M	USDA, APHIS, Animal Care	Date:
Title:	VETERINARY MEDICAL OFF	Jun-18-2008	
Received By:	(b)(6),(b)(7)(c)		Date:
Title:			Jun-18-2008

United States Department of Agriculture Animal and Plant Health Inspection Service

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Sep-11-2007

Inspection Report

CALVERT LABORATORIES INC Customer ID: 366

Certificate: 23-R-0107

SCOTT TECHNOLOGY PARK Site: 001

100 DISCOVERY DRIVE SCOTT TECHNOLOGY PARK

Type: ROUTINE INSPECTION

OLYPHANT, PA 18447 Date: Sep-11-2007

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(ii) IACUC: 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 training proposal includes the IV administration of 30% ethyl alcohol which can cause the animal pain and/or discomfort if the material is injected outside of the blood vessel. This is a potentially painful procedure and the principal investigator needs to provide a written narrative description of the search for alternatives to provide the IACUC adequate information for the review process and to comply with the animal welfare regulations. Correct by October 30, 2007.

2.31 (e) (2)

Title:

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(e)(2) IACUC: A proposal to conduct an activity involving animals must contain a rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

Animal activity proposal 0436S does not provide a rationale for the species and number of animals to be used that is specific for this proposal. The statement that the primate is a standard non-rodent species used in toxicology studies does not explain why primates were chosen over the other non-rodent species also commonly used such as rabbits and dogs. The statement that the number of animal used in this study is the minimum number necessary to obtain the required information is a generic generalization and does not address the justification for the specific numbers chosen for this proposal. The principal investigator must include a rationale for appropriateness of the species and numbers of animals to be used that specifically applies to the proposal to provide the IACUC sufficient information for the review process and to comply with the animal welfare regulations.

Correct by October 30, 2007.

Page 1 of 2



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Inspection Report

2.31 (e) (4)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(e)(4) IACUC: A proposal to conduct an activity involving animals must contain 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.

The training proposal includes the IV administration of 30% ethyl alcohol which can cause the animal pain and/or discomfort if the material is injected outside of the blood vessel. The proposal does not include a description of procedures to treat the animal and relieve the pain/discomfort. The proposal must include this information to ensure that animal pain and distress will be minimized.

Correct by October 30, 2007.

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Received By:

(b)(6),(b)(7)(c)

Title:

Date:

Date:

Sep-11-2007

Sep-11-2007