

United States Department of Agriculture Animal and Plant Health Inspection Service

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Inspection Report

Aragen Bioscience Inc. 380 Woodview Avenue

Morgan Hill, CA 95037

Customer ID: 35685

Certificate: 93-R-0504

Site: 001

ARAGEN BIOSCIENCE, INC.

Type: ROUTINE INSPECTION

Date: 22-SEP-2015

2.31(e)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Protocol 07-15-20-H2 does not contain an adequate rationale for the number of hamsters to be used in the activity. Animal use under the protocol has been completed and the protocol is no longer active. The protocol states In this study each group will have a minimum of 5 animals for a total of 35 animal (sic) with approximately 7 extra animals for weight match into groups. No rationale for the number of animals in each group or for the number of groups is provided in the protocol.

The Institutional Animal Care and Use Committee (IACUC) is responsible for ensuring that appropriate numbers of animals are used in each approved activity. In order to perform this function the IACUC must know both how many animals are needed for an activity and why that number of animals is needed. It is the responsibility of the IACUC to ensure that each activity involving animals contains and adequate rationale for the number of animals being used.

Correct immediately for all future protocols.

2.31(e)(5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

No method of euthanasia is described for animals undergoing terminal cardiac bleeds under deep anesthesia in protocol 01-15-16-CR. According to facility staff the method of euthanasia described for animals prior to anesthesia (CO2 inhalation) was not used on the animals undergoing terminal bleeds.

In order to ensure the wellbeing of the animals all methods of euthanasia should be appropriate for species and animal activities, and should be in accordance with American Veterinary Medical Association (AVMA) recommendations. The Institutional Animal Care and Use Committee (IACUC) should ensure that all pertinent methods of euthanasia are described in protocols prior to committee approval.

Correct immediately for all future protocols.

Prepared By: MARCY ROSENDALE, D V M USDA, APHIS, Animal Care Date:

02-OCT-2015

Title: VETERINARY MEDICAL OFFICER 5039

Received by Title: DELIVERED BY EMAIL Date:

02-OCT-2015

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2.33(a)(1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

There was no written program of veterinary care available for review at the time of the inspection.

The written program of veterinary care is needed to ensure that the facility understands the expectations of the attending veterinarian in regards to the veterinary care of regulated animals. The facility should ensure that the written program of veterinary care is completed by the attending veterinarian and is available for review during USDA inspections.

Correct by October 23, 2015

2.36(b)(6)

ANNUAL REPORT.

The facility s 2014 Annual Report of Research Facility did not reflect the fact that 376 cotton rats being used under protocol 01-15-16-CR should have been placed in Category D. According to the Annual Report the animals were included in Category C, however according to the protocol the animals were classified as Category D.

The failure to appropriately report animal use could negatively impact the ability of APHIS inspectors to monitor animal use. The facility should ensure that details regarding animal use are accurately portrayed in their Annual Report.

Correct by November 1, 2015.

An exit briefing was conducted with a facility representative.

Prepared By: MARCY ROSENDALE, D V M USDA, APHIS, Animal Care Date:

Title: VETERINARY MEDICAL OFFICER 5039

Received by Title: DELIVERED BY EMAIL Date: 02-OCT-2015

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
35685	93-R-0504	001	ARAGEN BIOSCIENCE, INC.	22-SEP-15

No Animals were Inspected.

Scientific Name Common Name Count 000000 NONE

NONE

000000 Total