

United States Department of Agriculture Animal and Plant Health Inspection Service

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Inspection Report

Univ Of Tennessee Knoxville Off Lab An Care

336 Ellington Plant Science

2431 Joe Johnson Drive

Knoxville, TN 37996

Customer ID: 843

Certificate: 63-R-0105

Site: 001

UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE

Type: ROUTINE INSPECTION

Date: 28-JUL-2015

2.31(c)(7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Review of IACUC records showed that the IACUC investigated a situation in which a total of ten research hamsters used on protocol 1626 showed adverse effects (lesions, illness and/or death) after a drug was administered in several different vehicles by several different injection methods in April 2015. The drug administered, the multiple vehicles used to administer the drug and the multiple injection routes used were not described in the approved protocol or any approved amendments to the protocol. The IACUC must review all proposed activities related to the care and use of animals in order to ensure that they meet all regulations and care standards. The IACUC shall 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. Corrected for protocol 1626; correct from this day forward for all future significant changes to protocols.

2.31(e)(3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

During this inspection three protocols reviewed by the inspectors were noted to not contain a complete description of the use of the animals:

*Protocol 2315 described three different dosage frequencies (BID, weekly or twice a week) for oral omeprazole. Review of animal records showed that omeprazole was being administered twice weekly.

*Protocol 1626 has an approved Jan. 13, 2014 amendment that includes SQ implantation of a device containing one of four named hormone replacements. No dosages or formulation information were given for the replacement hormones.

*Inspectors noted that cats on protocol 2149 were wearing Elizabethan collars and full length rear limb heavy bandaging. Cats were noted shaking their rear bandaged legs. The protocol contained no description of any bandaging or Elizabethan collar use for post-procedural care.

A protocol must contain a full complete description of the proposed use of the animals in order to allow the IACUC to complete a thorough protocol review. All proposals to conduct an activity involving animals or to make a significant change in an ongoing activity must contain a complete description of the proposed use of the animals. Correct by amending the above protocols by Dec.1, 2015.

Prepared By: SUSANNE BRUNKHORST, D V M USDA, APHIS, Animal Care Date: 31-JUL-2015

Title: VETERINARY MEDICAL OFFICER 1076

Received by Title: ATTENDING VETERINARIAN Date: 31-JUL-2015



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2.33(b)(3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Review of IACUC records showed that the IACUC investigated a situation in which a total of ten research hamsters used on protocol 1626 showed adverse effects after a drug was administered in several different vehicles by several different injection methods. Four hamsters injected with the drug subcutaneously on 4/15/15 developed skin lesions on 4/16/15. The research staff changed to intra-peritoneal injections and continued to inject the drug daily even though they were noted to be lethargic after the injection. Four hamsters were found dead on 4/20/15. Six hamsters were injected on 4/20/15 with different vehicles and were noted to be very sleepy and/or lethargic after the injection and injections were discontinued. Records show that PI staff monitored the animals and the adverse effects daily. Communication with the attending veterinarian for a veterinary consultation was not performed until 4/24/15 by the animal facility care staff who reported skin lesions on at least three hamsters. The six remaining hamsters were found to be ill by the vet tech staff on 4/28/15 and were euthanized on 4/28/15. Daily observation of all animals, with direct and frequent communication of problems to the veterinary staff, is critical to maintaining the health and well-being of the animals and to addressing all health issues in a timely and adequate manner. The facility shall ensure that daily observation of all animals to assess their health and well-being is being conducted and that there is a mechanism of direct and frequent communication so that timely and accurate information on problems of animal health, behavior and well-being are conveyed to the attending veterinarian. Correct from this day forward.

Exit conducted by Susanne Brunkhorst, VMO, Mary Ann McBride, VMO, undersigned Attending Veterinarian and additional facility representatives.

Additional Inspectors

Mcbride Mary Ann, Veterinary Medical Officer

Prepared By: SUSANNE BRUNKHORST, D V M USDA, APHIS, Animal Care Date:

Title: VETERINARY MEDICAL OFFICER 1076

Received by Title: ATTENDING VETERINARIAN Date: 31-JUL-2015

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
843	63-R-0105	001	UNIV OF TENNESSEE KNOXVILLE OFF LAB	28-JUL-15
			AN CARE	

Count	Scientific Name	Common Name
000029	Canis lupus familiaris	DOG ADULT
000003	Capra hircus	DOMESTIC GOAT
000021	Equus caballus	DOMESTIC HORSE
000021	Felis silvestris catus	CAT ADULT
000002	Lama pacos	ALPACA
000070	Mesocricetus auratus	SYRIAN / GOLDEN HAMSTER (COMMON PET/RESEARCH TYPE)
000005	Sus scrofa domestica	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000151	Total	