The Department of Agriculture has evidence that on or about June 10, 2011 and January 29, 2010, you or your organization committed the following violations of Federal Regulations:

2.31(c)(7) Institutional Animal Care and Use Committee (IACUC) ....repeated failure of the IACUC to review and approve, required modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activates

Titles 7 & 9 Code of Federal Regulations were promulgated to help prevent the spread of animal and plant pests and diseases and assure the humane treatment of animals. Since violations of the regulations can have serious and costly impact detrimental to the public interest, you are warned of this violation. Any further violation of these regulations may result in the assessment of a civil penalty or criminal prosecution. If you have any questions concerning this warning or violation, please contact the listed APHIS official.

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<th>APHIS OFFICIAL (Name and Title)</th>
<th>OFFICE ADDRESS:</th>
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<td>Robert M. Gibbens, Director</td>
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FOR PERSONAL SERVICE - RECEIVED BY: (Name and signature) |

FOR CERTIFIED MAIL - RECEIPT NO: 7011 0110 0001 6116 3522

APHIS FORM 7060 Previous editions may be used

PART 1 - VIOLATOR
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(c) IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

7) 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;

Changes regarding the care and use of animals in ongoing activities are not always being reported to the IACUC so that the IACUC can perform the required review and evaluation to determine whether it can approve the proposed change in the activity. Examples include:

--An IACUC approved protocol on rabbits described the procedures as occurring in 1 eye. Upon reviewing the health records of the rabbits, the procedure is occurring in both eyes. Surgery in both eyes may increase the amount of pain and/or distress that the rabbits will experience. There is no amendment to the protocol indicating the change in animal use.

--Calves, that are maintained tied in a stanchion for many days and are not able to make normal postural and social adjustments with adequate freedom of movement such as walking, are not getting the treadmill exercise as described in the IACUC approved protocol. Normal movement is important to the health and well-being of animals. This change was not reported to the IACUC for review and evaluation for possible approval.

The IACUC must be aware of changes to the protocols and evaluate them to determine whether the modification is in accordance with the Animal Welfare Act, Standards, and Regulations and whether they can approve the modification.

Correct from this point forward.
ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
   (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

The facility is not always using appropriate methods to treat with subcutaneous fluids, pain medications, antibiotics, eye medications, or to monitor the animals during anesthesia, even though they have established programs of veterinary care. Examples include:

--A kitten was given 10% dextrose by subcutaneous injection. The IACUC approved protocol states, "Any signs of initial malnutrition or dehydration will be treated with subcutaneous injections of no more than 5% glucose." Subcutaneous injections should not exceed a 5% concentration of dextrose, as this may dehydrate the animal further and does not meet veterinary standards. The animal subsequently died.

--A non-human primate was treated with Buprenorphine post-operatively and the interval between doses was greater than the recommended q 8-12 hours. The next day after the surgical procedure, the animal only received an 08:40 dose that was almost 15 hours after the previous dose of Buprenorphine. The animal may have been subsequently demonstrating pain when observed "not moving from corner. Didn't eat very much." Pain medications must be given in a timely manner to prevent pain.

--Two pigs are noted at the time of inspection to be toe-touching to non-weight bearing lame on the limbs that had a surgical procedure performed approximately 2 weeks prior. One of the pigs has been noted as NOA (no observable abnormalities) on its health record on this day and the other pig had been examined by the veterinarian the day prior for "favoring" the right rear leg, but analgesic therapy had not yet been initiated at almost 15:00. Early recognition and treatment of pain and distress are important to the health and welfare of the animals.

---The veterinarian gave orders that a cat with a fever was to receive Amoxi 1 ml BID x 7 days. The cat received Amoxi on 2/4/09 at 08:45 and 15:26; on 2/5 at 08:59 and 15:50; on 2/6 at 08:43 and 15:45; on 2/7 at 07:05 and 10:04; on 2/8 at 07:26 and 10:17; 2/9 at 09:05 and 17:05; and 2/10 at 08:47 and 16:21. Some of the intervals are 15 to almost 23 hours apart. Another cat in this same study similarly received Amoxi at inappropriate intervals from 7/16-22/09 for a sore on the tip of its tongue. A wood rat is being treated with the antibiotic Baytril BID. The intervals between doses should be approximately 12 hours, but is sometimes as great as 20 hours. Antibiotics are not as effective when given at inappropriate intervals and this may endanger the animal.

--A rabbit whose surgical eye procedure was performed 1-25-10 was to receive Polytrim 3 times a day for one week and Pre Forte 3 times a day for 5 days. Three times a day would mean approximately 8 hours between doses. On 1/26/10, the rabbit only received the Pred Forte 2 times at 10:05 and 15:10 and the Polytrim at 06:35, 09:58, and 15:00. On subsequent days, the dosing intervals continued to be inappropriate and were given as close together as 3 doses in less than a 10 hour span. Similar dosing schedules were used on 2 other rabbits.

Prepared By: JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care Title: VETERINARY MEDICAL OFFICER Inspector 5022

Received By: (b)(6),(b)(7)(c)

Date: Mar-24-2010

Date: Mar-22-2010
--The facility is not always using appropriate methods to monitor procedures involving anesthesia. A cat received the injectible anesthetic at 13:38. It was monitored at 14:12 and 14:14 only, according to the record. Extubation occurred at 14:52. Another cat evidently received inadequate anesthesia monitoring on 2/13/09. The IACUC approved monitoring procedures require: "Write in data at least every 15 minutes during surgery." The facility needs to follow the IACUC approved procedures for monitoring the administration of anesthesia to ensure the safety of the animal.

The facility needs to ensure that appropriate methods to prevent, control, diagnose and treat diseases and injuries are consistently applied, including the use of correct fluids, drug dosing intervals, prompt administration of pain relieving drugs, and timely monitoring during anesthesia.

Correct from this point forward.

3.28 (c) (1) (iii)
PRIMARY ENCLOSURES.

Each guinea pig shall be provided a minimum amount of floor space in any primary enclosure as follows: from weaning to 350 gr = 60 square inches, > 350 gr = 101 square inches, and nursing females with their litters = 101 square inches.

--It was noted at the time of inspection that one primary enclosure of guinea pigs was overcrowded. The facility measured the enclosure while the USDA inspectors were on site and agreed that the floor space did not meet AWA Standards. Space requirements need to be followed to avoid problems to the health of the animals that can occur with overcrowded conditions.

Corrected at the time of inspection.

3.81 (c) (4)
ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

(c) Special considerations. Certain nonhuman primates must be provided special attention regarding enhancement of their environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Nonhuman primates requiring special attention are the following:

(4) Individually housed nonhuman primates that are unable to see and hear nonhuman primates of their own or compatible species;

--There is no evidence that the individually housed non-human primate (NHP) was receiving special attention regarding enhancement of its environment. It did not have a signed exemption from the

Prepared By:

JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 5022

Date: Mar-22-2010

Received By: 

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

Date: Mar-24-2010
Inspection Report

Attending Veterinarian to approve individual housing, instead of the standard social grouping, in accordance with the facility's IACUC approved Program for Environmental Enhancement for NHPs and 3.81(e). The facility's IACUC approved program needs to be followed to ensure the health and well-being of the NHPs and compliance with 9CFR 3.81.

Correct from this point forward.

The USDA, APHIS, ACVMO inspectors, Dr. Judy Davis and Dr. Tonya Hadjis, were accompanied at various times during the 5 day inspection from 1/25-29/10 by the Attending Veterinarian, the IACUC Director, and the Director of the animal resource department, and for a period of time on 1/26/10 by a representative from OLAW.

Prepared By: JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER Inspector 5022
Date: Mar-22-2010

Received By: (b)(6), (b)(7)(c)
Title: 
Date: Mar-24-2010
2.33 (b) (2) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

The facility is not always using appropriate methods to treat with antibiotics or to monitor the animals during anesthesia, even though they have established programs of veterinary care. Examples include:

--An eleven day old kitten began a veterinarian prescribed twice daily treatment with Amoxicillin on 4/6/10. On 4/7/10, the Amoxicillin was given at 09:00 am and approximately 15:00. The next dose was given on 4/8/10 at approximately 07:00 am. This is an interval of 16 hours between doses. Twice daily antibiotics should be given at intervals of approximately 12 hours. Antibiotics are not as effective when given at inappropriate intervals and this may endanger the animals.

--A primate was anesthetized for 20 minutes while the veterinarian sutured the primate's finger. No evidence of monitoring during the procedure could be furnished. The IACUC approved monitoring procedures require: "Write in data at least every 15 minutes during surgery." The facility needs to follow the IACUC approved procedures for monitoring anesthesia to ensure the safety of the animals.

The facility needs to ensure that appropriate methods to prevent, control, diagnose and treat diseases and injuries are consistently applied, including the use of correct drug dosing intervals and appropriate monitoring during anesthesia.

Previous correction date assigned on 3-24-2010 was "from this point forward".

Exit interview was conducted with the Directors of the Office of Comparative Medicine and the IACUC.

Prepared By:

JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 5022

Date: Jun-10-2010

Received By:

Date: Jun-11-2010

Title: 

(b)(6),(b)(7)(C)
ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
   (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the
       availability of emergency, weekend, and holiday care;

--The facility is not always using appropriate methods to prepare for aseptic surgery. A craniotomy on a primate was
performed on 7/12/10 in a surgery area that had been used for another animal procedure several days earlier and not
prepared afterwards as an aseptic surgery area. The IACUC approved protocol for this procedure called for an
aseptically prepared surgery area. Maintenance of an aseptic surgery room is important during major operative
procedures to prevent infection. The research facility shall maintain programs of adequate veterinary care that
include the use of appropriate methods to prevent and control diseases such as aseptically prepared surgery areas
for major operative procedures.

Correct immediately.

--The facility has outdated drugs ready for use, not labeled as expired, and commingled with non-expired drugs. The
expired drugs included Tequin (expiration 10/2005), Trepicamide Solution (Expiration 11/2007), Gonak (one with
expiration 9/2008 and one with expiration 4/2007). Expired drugs may be ineffective, toxic, or contaminated with
bacteria, and could injure the animals. The facility must establish and maintain programs of adequate veterinary care
that ensure drugs used on the animals are safe and effective.

Correct immediately.

HOUSING FACILITIES, GENERAL.

Open food and bedding supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and
contamination.

--Two bags of open cereal used for marmoset treats are stored in a file drawer and not in sealed
containers to prevent contamination. Open food supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination.

Correct by 7/15/10.

Inspection conducted with Attending Veterinarian and IACUC Director. Exit interview was conducted with IACUC Director. Tracy Thompson, USDA, APHIS, AC, VMO was also present for the inspection and exit interview.