



Inspection Report

Vanderbilt University Medical Center
1161 21st Ave S Mcn Aa 6206
Nashville, TN 37232

Customer ID: **335389**
Certificate: **63-R-0129**
Site: 001

VANDERBILT UNIVERSITY VICE PROVOST FOR RESEARCH

Type: ROUTINE INSPECTION
Date: 19-FEB-2020

2.33(b)(5) DIRECT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

During this inspection six New Zealand white rabbits were observed on protocol M1800146 which involves intravitreal drug injections into the eyes of rabbits. These six rabbits had received an injection of the test drug the day before they were inspected. On the morning of the inspection day all six rabbits had abnormalities associated with one or both eyes ranging from mild focal swelling around the eye and mild redness to more serious changes. Three of the rabbits (#113329, 113330 and 113331) had more serious issues including more severe swelling, redness, tear production and holding one or both eyes completely closed. Two of these three rabbits sat facing the back of their cage even while people were looking at them although they did move about when their cage door was opened. In addition, small mounds of pelleted rabbit feed were noted being dumped out for disposal as fresh pellets were being placed in the hoppers by the husbandry caretaker. The lab staff member also present in the room stated that this was done to monitor the rabbit's feed intake. Based on the amounts of pellets being discarded versus the new daily ration, it appears that many of these rabbits had eaten much less than half of the daily ration for the past 24 hours. The lab staff member stated that the eye issues and decreased appetite were normal/to be expected and would clear up on their own in 1-2 days as she had observed after previous injections. The approved protocol stated 'significant periocular swelling that was symptomatic or adversely affected rabbit behavior was very rare' and that 'redness of the eye, subconjunctival hemorrhage and squinting...are self-limiting and go away in 1-2 days'. The protocol did not include any specific monitoring parameters or treatments for the eye issues observed during the inspection. Review of procedural records of the previous drug injections administered to these rabbits also showed several similar eye issues being noted/monitored by both lab staff and veterinary staff post-injection but no treatments were documented. A few hours after the inspection of these six rabbits, the three most severely affected rabbits were examined by the lab staff and a clinical veterinarian. All were diagnosed with periocular swelling/irritation. Tear production was noted. Treatment consisted of lubricant drops for all three and two were given ketoprofen. Follow up exams and treatments were provided. The eye issues of two of the rabbits cleared up within 48 hours. The third rabbit (#113330) is improving but is still being treated five days later. As part of the inspection, a review of all of the procedural records for these six rabbits was conducted. It was observed that at the start of the study the rabbits were given an intravitreal injection of disease causing cells. The

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protocol was unclear about whether or not pre and post procedural analgesics were to be administered for this part of the study. In one section it stated that the analgesic ketoprofen would be administered every 12 to 24 hours. In another section it simply stated that analgesics may be administered. The records reviewed documented that ketoprofen was not administered to any of the rabbits before, during or after the procedure. According to the post-procedural records, all six rabbits developed eye redness. Three of the rabbits (#113329, 113327 and 113325) showed weight loss (5-7%) and had decreased fecal +/- decreased urine output. These animals were examined by a veterinarian and the poor appetite was addressed via diet changes.

Adequate pre- and post-procedural care is necessary to ensure that procedures involving rabbits will avoid or minimize discomfort, distress and pain to the animals. Rabbits, as a prey species, are more difficult than other species to evaluate regarding discomfort, distress and pain so subtle changes in appetite, fecal and urine production and behavior such as facing away from a potential predator (people) or holding eyes closed/squinting need to be closely observed and identified post procedures. If such changes are noted, post-procedural treatment should be provided unless treatment would adversely affect the results or interpretation of the research and such has been approved in the protocol by the IACUC (not the case in the current protocol). The research facility shall establish and maintain a program of adequate veterinary care that includes adequate pre- and post-procedural care in accordance with current veterinary medical and nursing procedures. Corrected during this inspection.

This inspection was conducted over three days-Feb. 19, 20 and 24 with the Associate Director of Clinical Medicine DAC, an OAWA representative and other facility representatives. The exit interview was conducted on Feb. 25 with the undersigned Attending Veterinarian, the IACUC Chair and other facility representatives.

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
335389	63-R-0129	001	VANDERBILT UNIVERSITY VICE PROVOST FOR RESEARCH	19-FEB-20

Count	Scientific Name	Common Name
000009	<i>Canis lupus familiaris</i>	DOG ADULT
000002	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000048	<i>Galago senegalensis</i>	NORTHERN LESSER BUSHBABY
000003	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000039	<i>Macaca mulatta</i>	RHESUS MACAQUE
000004	<i>Macaca radiata</i>	BONNET MACAQUE
000197	<i>Meriones unguiculatus</i>	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000012	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000004	<i>Ovis aries aries</i>	SHEEP INCLUDING ALL DOMESTIC BREEDS
000001	<i>Saimiri boliviensis</i>	BLACK-CAPPED SQUIRREL MONKEY
000012	<i>Saimiri sciureus</i>	COMMON SQUIRREL MONKEY
000004	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000008	<i>Tupaia glis</i>	COMMON TREE SHREW
000343	Total	