

23R0036

November 30, 1999

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UNITED STATES DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service
Regulatory Enforcement and Animal Care
Eastern Region Office
920 Main Campus Drive
Raleigh, NC 27606

DEC 01 1999

Re: Registration Number 22-R-0036

Dear Dr. Goldentyer:

Listed below are comments to accompany the annual report of research facilities for site number 1.

One exception to the canine exercise program is to be reported. It involved the use of special canine metabolism cages for drug metabolism studies. The canine metabolism cages provide greater than 100%, but less than 200% of required space for exercise. The animals must remain in the cages for the proper and safe collection of the metabolites. The period of time is usually less than 10 days. Positive human interaction is greatly increased during this period. The protocols with the exemption are approved by the IACUC and reviewed during the semi-annual program review. The studies are infrequent and involved only twelve laboratory canines.

The environmental enrichment program has two exceptions for paired housing for nonhuman primates. Twenty-one squirrel monkeys and twenty-eight rhesus were housed separately for special study needs for controlling and monitoring food consumption as part of the research projects. Thirty-two cynomolgus monkeys were housed separately for brief periods for proper metabolite collection studies. All the animals are included in all the other aspects of the environmental enrichment program. The protocols with the exemption are approved by the IACUC and reviewed during the semi-annual program review.

Listed below are comments to accompany the annual report of research facilities for site number 2.

The dogs, rabbits and nonhuman primates listed in column "E" animals were used in federally mandated toxicological investigations for new drug development. Because one purpose of toxicologic studies is to define the pharmacokinetic and metabolic profiles of new entities, potential drug interactions are not known during the course of the studies. Administration of anesthetics, tranquilizers, and/or analgesics could result in additive toxicities which would be detrimental to the animal's well-being. In addition, the administration of such drugs could diminish the ability of the scientists to detect clinical changes which are critical to determining the toxicity of the compounds. These agents were, therefore, withheld in accordance with protocols which are carefully reviewed and approved by the IACUC.

All animals are carefully monitored and if found to be in severe pain and/or distress during the course of the study, they are provided humane euthanasia. Animals, in which adverse clinical findings were identified but were not determined by the Staff Veterinarian to be of a severe nature, were allowed to continue to the completion of the study, but are also reported in column "E" of this annual USDA report.

USDA Fiscal Year 1999 Exemptions from Site 2 for Animal Care and Use

Instances wherein animals were exempted from the pair-housing requirement of our program for the psychological well being of non-human primates. The duration of such exemptions varied according to the reason. The numbers of animals and reasons for such exemptions are herein listed:

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1. Non-human primates were exempted from social housing when required for collection of individual clinical signs and required randomization of the animals in studies. The exemption from social housing is variable and can range from 2 weeks to 6 months, depending on the duration of the individual study. All study protocols were reviewed and approved by the IACUC. 416

2. Primates exempted from social housing due to a transient medical condition as specified by the Staff Veterinarian, the duration of the exemption varies depending upon the medical condition. 25

3. Primates exempted from social housing due to being the documented aggressor in a pair housing situation on at least two occasions, these exemptions will be ongoing 2

There were 182 dogs exempted from our exercise program for dogs during the dosing period of studies where necessary to avoid emesis. All protocols including this exemption were reviewed and approved by the IACUC.