

31R0089

USDA ANNUAL REPORT-REPORTING PERIOD: OCTOBER 1, 1998 THRU SEPTEMBER 30, 1999FACILITY REGISTRATION NUMBER: 31-R-0089REPORTABLE EXCEPTIONS TO ANIMAL WELFARE ACT (continued)-

(feeding, cage cleaning, etc.). These three studies were on the same exercise and socialization regimen for a period of approximately 30 minutes seven days per week.

The Attending Veterinarian exempted one male dog on a subchronic toxicity study from exercise on March 4, 1999 due to an ocular discharge. The animal, upon re-examination by the Veterinarian after March 4, 1999, was allowed to return to the normal exercise/socialization regimen for this study.

The Attending Veterinarian exempted one male dog on a chronic toxicity study for one day's exercise period (2/7/99) due to a swollen right hind paw. The Veterinarian rechecked the animal after this exempted day and was then returned to the normal exercise and socialization regiment for this study.

The 36 dogs on a one-week reproductive toxicology study were exempted from exercise/socialization for three days after blood collection after pre-study blood parameters were collected. The purpose of this study was to investigate the reproductive system toxicology when given to mature beagle dogs for up to one week. The study was conducted in compliance with the U.S. FDA Good Laboratory Practice Standards, 21 CFR Part 58, with the exception of the hormone analyses and the histological processing of the hypothalami and pituitary glands.

Eight male and eight female beagle dogs were used in a FDA-regulated 14-Day Inhalation Range-Finding Study. The purpose of the study was to evaluate the possible toxic effects of the test article when administered via nose-only inhalation to dogs for 14 days and to provide information to guide dose selection for a 90-day study. The dogs were given regular opportunity for exercise/socialization during the 20-day acclimation/pretreatment period. The animals were exempted from exercise during the 14-day exposure period due to the nature of the test article, which is known to cause large increases in heart rate. The exemptions were approved to minimize the excess risk and distress to the animals. The animals were given a great deal of human attention every day to reduce the potential for stress.

ANIMAL WELFARE ACT COMPLIANCE STATEMENT

(This statement is included in all animal study protocols)

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9CFR). The Sponsor should make particular note of the following:

1. The Sponsor signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.
2. Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory Standard Operating Procedures.

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3. Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely manner as possible.
4. Methods of euthanasia used during this study are in conformance with the above-referenced regulation.