

USDA Annual Report
Registration #: 22-R-0145

Explanation of Category 'E' Animals

1. Number of Animals and Species Used in:

General Toxicology

Used: 105 Dogs

Number of Category E animals: 10

2. Procedure Used:

General Toxicology

2 dogs: During a single dose study range finding study, two animals displayed marked decreased activity. The animals were monitored throughout the study and the veterinarian determined that the signs were not severe enough to remove the animals from study.

8 dogs: In a oral toxicity study for a potential oncological medicine, eight animals displayed mild to marked decreased activity, vomiting and liquid feces. One was found dead and five were humanely euthanized prior to the end of study.

During all studies, the dogs were under veterinary supervision and treated as appropriate.

3. Justification for procedure:

General Toxicology

National and international regulatory agencies require safety studies prior to the approval of any new drug. These assessments safeguard the human population from potentially harmful effects from experimental candidates and new drug products. The goal of these studies is to investigate the toxicity of a new drug or formulation.

4. Procedure required by:

Reproductive & General Toxicology Studies: Agency: FDA; Federal Food, Drug, and Cosmetic Act CFR: 505 (4) (i) (1) (A)

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