Facility Registration Number 16-R-0029

E.4

Five dogs assigned to Column E of this report were used in non-clinical laboratory studies to evaluate the safety of test compounds in accordance to Food and Drug Administration requirements under Good Laboratory regulations 21 CFR 58. The animals were used on studies to determine the potential target organs of toxicity and no effect levels of test articles that were administered. These animals exhibited one or more clinical signs on one or more days that included diarrhea, weight loss, and/or decreased activity. The dogs were not given other drugs such as analgesics or sedatives that might cause reversal of histological toxic effects of test article or induce their own inherent toxicities or drug-drug interactions. Animals were, however, provided fluids, nutritional supplements and other palliative care that mitigated these signs.