

Appendix 1  
USDA ANNUAL REPORT (2018-2019)  
Registration #: 22-R-0138

Species/protocol	Cat E usage	Procedure/Justification
Dogs	14	<p>Pharmacokinetic/Toxicology studies. Animals received multiple (oral) doses of investigational compounds</p> <p>These dogs experienced multiple episodes of vomiting and/or diarrhea after receiving multiple oral doses of test compounds.</p> <p>Anesthetics, analgesics and/or tranquilizers could not be administered because they may interfere with the goals/aims of the studies which are to determine the absorption and toxicity profile of the dosed investigational agents. These studies are performed in accord with ICH: "Guidance for Industry M3(R2) Nonclinical Safety Studies for The Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals," dated January 2010.</p> <p>(In all cases, this met the IACUC approved study endpoint criteria)</p>

Exemptions: none