Appendix 1
USDA ANNUAL REPORT (2015-2016)
Registration #: 22-R-0138

Species/protocol	Cat E usage	Procedure/Justification
Dogs	10	Pharmacokinetic/Toxicology studies. Animals received multiple (oral) doses of investigational compounds *These dogs experienced multiple episodes of vomiting and/or diarrhea after receiving multiple oral doses of test compounds.* 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 On Nonclinical Safety Studies for The Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals M3(R2)," dated 11 June 2009. *(In all cases, this met the IACUC approved study endpoint criteria)*
Rabbits	28	Anti-infective studies. Animals were injected with bacteria to study efficacy of anti-infective compounds. *Rabbits were infected via a surgically subcutaneously implanted wiffle ball or were injected intravenously to create a bacteremia. These animals developed a fever and decreased appetite and for approximately 24 hrs.* Administration of analgesics will adversely affect the ability to analyze & evaluate these effects. *(In all cases, this met the IACUC approved study endpoint criteria)*

Exemptions: none