

NOV 30 2016

A. Column E Explanation (all studies listed below were approved by the IACUC at their respective site):

Forty-seven hamsters developed terminal complications as part of an infectious disease study. The animals were closely monitored and those animals identified with significant health issues were humanely euthanized. The animals being reported died after a sudden onset of the disease before euthanasia could be accomplished.

Six rabbits developed acute terminal complications while on toxicology studies and died before euthanasia could be accomplished.

Two dog developed acute complications while on a toxicology study and died before euthanasia could be accomplished. Six dogs developed signs of weight loss and inappetence while on a toxicology study. A decision was made to euthanize the dogs.

The activities and procedures of conduct for the above-referenced studies were reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). Animals used on product release testing and toxicology studies were required by federal regulations for submission regarding safety and toxicity testing. The regulations that require these procedures include 21 CFR 58 (FDA) and 21 CFR 610.11 (FDA).