

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

One rabbit developed per acute complications while on a toxicology study and died before euthanasia could be accomplished.

One non-human primate developed acute complications while on a toxicology study and died before euthanasia could be accomplished.

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 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).