

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

One guinea pig developed acute complications while on a product-release testing study and died before euthanasia could be accomplished.

Two rabbits developed acute complications while on toxicity studies and died before euthanasia could be accomplished.

One non-human primate developed acute complications while on a toxicity 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 are required to be used on product release testing and toxicology studies 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).

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