Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addressed, protocols, veterinary care programs, and the like, are not required as part of an explanation. Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 91-R-0011.

2. Number 26 of animals used in this study.

3. Species (common name) Guinea Pigs of animals used in the study.

4. Explain the procedure producing pain and/or distress.

Guinea Pigs are used for the performance of the Food and Drug Administration directed General Safety Test, as defined in 21 CFR Part 610.11. The animals are given an intraperitoneal injection (part 610.11, c, 1) of up to 5mL of a product that is generally regarded as safe and non-toxic. The overt health of the animal is monitored for a seven day period, at which time the test is concluded. A failed test is indicated by either death or weight loss of the animal. Product interaction may be attributed to either of these results.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

Anesthetics, analgesic or tranquilizing drugs are not administered, as they may interfere with the test results. The product may induce a pyrogenic response, potentially resulting in weight loss and/or death, which would be masked by these drugs. At any time during the test an animal that appears to be ill and/or suffering, it will be humanely euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: DHHS-FDA, CBER CFR 21 CFR 610.11 General Safety

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NOV - 2