

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, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 34-R-0027

2. Number 5199 in column E of animals used in this study.

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

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

Animals receive either virulent organisms or toxins in vaccination/challenge studies to evaluate potency of vaccine products.

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)

Death or survival is the endpoint used in the evaluation of vaccine products. The use of analgesics has the potential for causing misinterpretation of test results, and could alter time to death. Animals challenged with organisms die within hours of becoming ill. Animals challenged with toxin are considered dead and are removed from the test when moribund.

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 FDA 21CFR 610.10; 600.3(5)

- 1) Product License 1260/103821
- 2) USP Method (Monograph, Pharmacopeial Forum, July-August 2003, page 1002)