

42R0020

Optional Column E Explanation Form

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: 42-R-0020
2. Number 2181 of animals used in this study.
3. Species (common name) hamster of animals used in this study.
4. Explain the procedure producing pain and/or distress.

Refer to number 6 below.

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 question 6 below)

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 USDA, APHIS, VS, CVB CFR

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1. Registration Number: 42-R-0020
2. Number 2 of animals used in this study.
3. Species (common name) guinea pig of animals used in this study.
4. Explain the procedure producing pain and/or distress.

The procedure is potency test for *Clostridium tetani* antitoxin in which 2 control animals are ~~lethal dose~~^{not} given a lethal dose of Tetanus toxin. By definition, the control animals must be down and unable to rise or stand under their own power.

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 question 6 below)

This is a required potency release test - see 9CFR 113.451

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 APHIS CFR 64