

## Column E Explanation

USDA ANNUAL REPORT (2014-2015)

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1. Registration number \_\_\_\_\_ 22-R-0138 \_\_\_\_\_
2. Number \_\_\_\_\_ 44 \_\_\_\_\_ of animals used in this study.
3. Species (common name) \_\_\_\_\_ Dog \_\_\_\_\_ of animals used in the study.
4. Explain the procedure producing pain and /or distress.

*After being orally dosed with test compound:*

*36 of these dogs experienced two or more episodes of vomiting and diarrhea,*

*4 showed mild neurologic signs lasting less than one hour, and*

*4 had tremors lasting from one to seven days.*

5. Attach or include an explanation with the reason(s) for why anesthetics, analgesics and tranquilizers could not be used. (For Federally mandated testing, see item 6 below)

*Pain and/or distress could not be relieved with anesthetics, analgesics, tranquilizers, anti-emetics or anti-diarrheals as they will interfere with the goals/aims of the intended studies, primarily study of the physiologic and pathologic processes produced by toxicity of dosed investigational agents.*

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):

*These studies are performed in accord with "Harmonization of Guidelines for Toxicity testing of Pharmaceuticals by 1992," regulatory Toxicology and Pharmacology, Vol 12, 179-211 (1990).*

Agency \_\_\_\_\_ CFR \_\_\_\_\_

## Column E Explanation

USDA ANNUAL REPORT (2014-2015)

1. Registration number \_\_\_\_\_ 22-R-0138 \_\_\_\_\_
2. Number \_\_\_\_\_ 52 \_\_\_\_\_ of animals used in this study.
3. Species (common name) \_\_\_\_\_ Rabbit \_\_\_\_\_ of animals used in the study.
4. Explain the procedure producing pain and /or distress.

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*After being intravenously inoculated with bacteria or receiving a vaccine intramuscularly rabbits developed a fever lasting between 2 and 48 hours.*

5. Attach or include an explanation with the reason(s) for why anesthetics, analgesics and tranquilizers could not be used. (For Federally mandated testing, see item 6 below)

*Pain and/or distress could not be relieved with the administration of anesthetics, analgesics, tranquilizers or antipyretics as this will diminish the pathogenicity of the bacteria being evaluated. In addition they will interfere with vaccine efficacy, immunogenicity and pyrogenicity.*

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 \_\_\_\_\_ CFR \_\_\_\_\_