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: 35-R-0030

2. Number 6 (of the 20 on study) 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.

Rabbits were administered routine test article formulation for the purpose of ***(b)(4)***
(b)(4) Pain and/or distress were not anticipated as a study outcome.

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)

(b)(4)

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

N/A

Agency_____ CFR_____

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1. Registration Number: 35-R-0030

2. Number 468 (of the 1040 on study) 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.

Rabbits were administered experimental (b)(4) (b)(4) to study the (b)(4) Rabbits receiving the (b)(4) with certain configurations may exhibit (b)(4) (b)(4) lasting a few hours post (b)(4) .

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)

The Center for Biologics Evaluation and Research (CBER, FDA) requested that rabbit data be included in evaluations of the experimental (b)(4) . Treatment of the rabbits to ameliorate (b)(4) would reduce the ability to determine optimal (b)(4) of the experimental (b)(4) necessary to select the safest (b)(4) for human trials. Therefore, the study design included close monitoring of (b)(4) in the rabbits up to pre-determined end points. Typically, rabbits that exhibited (b) (4) spontaneously resolved within 18-24 hours; however, if pre-determined end points were reached at any point during the study, veterinary interventions (b)(4) (b)(4) were implemented to minimize pain and distress. Suspension of veterinary intervention unless rabbits met pre-determined end points was necessary to fulfill the study purpose (b)(4)

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

N/A

Agency_____ CFR_____