

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: 48-R-0111
2. Number 2 of animals used in this study.
3. Species (common name) Cat of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Cats underwent onychectomy (declaw) of the front limbs. The two cats were documented as being reluctant to place weight on their front paws.

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 intent of the study was to investigate the pain relieving efficacy of two compounds in cats undergoing onychectomy. Procedures were in place to minimize pain and discomfort if necessary, which included administration of analgesics. The pain levels experienced, however, did not exceed the established pain threshold set forth in the protocol to warrant additional analgesics.

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):

Though the FDA does not require this procedure perse, compounds must show efficacy in relevant preclinical studies. Onychectomy was chosen as it is a very common and often painful procedure, regularly conducted in cats. Onychectomy was chosen over other more invasive procedures, such as ovariohysterectomy, which would require longer surgical and recovery periods.

Agency _____ CFR _____

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