Column E Explanation

This form is intended as an aid to complete the Column E explanation. It is not an official form and its use is voluntary. Annual Reports and explanations should NOT include PII information such as names (principle investigators and research staff), addresses, protocols, meeting notes (either in part of in full), the animals room numbers, grant information, veterinary care programs, and the like. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: **33-R-0152**

2. Number **6** of animals used in this study.

3. Species (common name) _**Dog**__ of animals used in this study.

4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

Animals were involved in pre-clinical drug safety studies mandated by 21 CFR 312.23(a)(8)(ii) and 21 CFR 314.50(d)(2) to determine safety of new pharmaceuticals prior to human trials and eventual approval for human use. The drug safety studies conducted caused an elevated body temperature that, based on past experience, was unresponsive to the administration of antipyretics and, thus were withheld to avoid adding study variability. Earlier studies revealed that the increased body temperatures were transient, relative to dosing and returned to within normal range with no additional significant clinical signs (i.e. seizures, lateral recumbency, unresponsiveness, etc.); thus, rescue efforts were not warranted.

6. What, if any, federal regulation 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_____**21 CFR 314.50(d)(2) &_21 CFR 312.23(a)(8)(ii)**
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