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0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2021

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER

33-R-0152

2. Research Facility Headquarters address

1 N. Waukegan Rd
North Chicago, IL 60064

3. Number of animals used in the study.

1

4. Species (common name) of animals used in the study. Dog

5. Explain the procedure producing pain and distress.

Pre-clinical safety study.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

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. Earlier studies revealed that mild to moderate neurologic signs, decreased appetite, and emesis were expected relative to dosing. Since intervention would interfere with interpretation of the results of this study, a humane endpoint of any clinical signs beyond those previously experienced was established to minimize undue pain and distress. Increased monitoring was implemented to minimize adverse animal welfare effects. One dog experienced neurological effects that warranted euthanasia on day 4 of dosing which led to lowering the dose for the high dose group for the remainder of the study.

7. 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):

21 CFR 312.23(a)(8)(ii) and 21 CFR 314.50(d)(2)

Agency	CFR
FDA	21 CFR 312.23(a)(8)(ii)