

FEB 09 2009

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 211

See attached form for additional information.

Interagency Report Control No. *A*

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 63-R-0105 CUSTOMER NUMBER: 843	FORM APPROVED OMB NO. 0579-0038
	Univ Of Tennessee Knoxville Off Lab An Care 2621 Morgan Circle Dr Knoxville, TN 37996 Telephone: (865)-974-7342 <i>2007-2008</i>	

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		34	37	8	79
5. Cats	13	19	21		40
6. Guinea Pigs		4			4
7. Hamsters		6	452		458
8. Rabbits		4	11		15
9. Non-human Primates					
10. Sheep			8		8
11. Pigs			3		3
12. Other Farm Animals					
Goats		12			12
13. Other Animals					
Hlama		14			14
Cattle		25			25
Horses		45	93		138

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rest teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
 (Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (6)(7)(C)

DATE SIGNED

11/19/08

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.

63-R-105

1. Registration Number: _____

2. Number 8 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.

A momentary (two seconds) noxious electrical stimulus is administered to determine analgesic efficacy based on physiological response after injection of Buprenorphine. The electrical stimulus is transient in nature and does not produce tissue damage.

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)

This is a pharmacokinetic and pharmacodynamic study to develop a sustained release Buprenorphine formulation for a single injection for prolonged analgesia in dogs. Preliminary data has been collected in studies involving mice. Formulations need to be established for dogs. Please see references ;

4. Yu S, Zhang X, Sun Y, Peng Y, Johnson JR, Mandrell T, Shukla AJ, and Laizure SC. (2006) Pharmacokinetics of buprenorphine after intravenous administration in mouse. JAALAS 45(3); 12-17.
5. Shukla AJ, Qu W, et al. Analgesic effect in mice following a subcutaneous injection of suspensions of buprenorphine in three different vehicles. Poster Presentation, AAPS annual meeting, 2007. Manuscript preparation in progress.
6. Shukla AJ, Qu W, et al. Buprenorphine plasma concentration profiles in mice after subcutaneous injections of three different suspensions of buprenorphine in mice. Poster Presentation, AAPS annual meeting, 2007. Manuscript preparation in progress.

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):

N/A

Agency _____ CFR _____