

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )	1. CERTIFICATE NUMBER: 14-R-0150 CUSTOMER NUMBER: 10717	FORM APPROVED OMB NO. 0579-0036
Alkermes Inc 88 Sidney St Cambridge, MA 02139  Telephone: (617) -494-0171		

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 ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o 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, experments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reaso such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs			142	20	162
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**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 research, 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 )

TE SIGNED  
 125/05

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NOV 29 2005



## Attachment A

### Explanation RE: guinea pigs not receiving anesthesia or analgesia (Column E)

Animals not receiving anesthesia or analgesia were used in a citric acid induced cough procedure under Alkermes IACUC protocol 03-3A, "Antitussive and bronchorelaxant effects of local anesthetics and bronchodilators alone and in combination, in guinea pigs". The actual citric acid challenges that evoke cough have never been conducted under anesthesia, either in our laboratory or in the reported literature. The two primary reasons for this are: 1) In order to mimic the clinical setting, where volunteers for studies remain conscious during tussigenic challenges, as closely as possible and 2) Afferent impulses triggering cough appear to be mediated through at least two subtypes of airway sensory fibers, A8 "cough receptors", and slowly-conducting C fibers. While a number of stimuli known to evoke cough in humans and guinea pigs (e.g., capsaicin, bradykinin, SO<sub>2</sub>) anesthetized guinea pig (reviewed in Canning, Pulm Pharm & Ther, 2002). This means the cough in anesthetized guinea pigs is driven entirely by the "cough receptors". While this setting could be informative when investigating the role of the "cough receptors", it does not reflect the normal physiology of cough.

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November 25<sup>th</sup>, 2005

Elizabeth Goldentyer, DVM  
Regional Director – Animal Care  
USDA  
APHIS  
920 Main Campus Drive  
Suite 200  
Raleigh, NC 27606

Dear Dr. Goldentyer:

Please find herewith the Alkermes Annual Report of Research Facility for Fiscal Year 2005 documenting facility activities and animal usage as required under the Animal Welfare Act.

Alkermes operates only a single animal facility. This facility is located at 88 Sidney Street Cambridge, MA 02139.

Sincerely,     A

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