United States Department of Agriculture
Animal and Plant Health Inspection Service

Annual Report of Research Facility

<table>
<thead>
<tr>
<th>Certificate Number: 14-F-0009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer Number: 463</td>
</tr>
<tr>
<td>U.S.D.A./Human Nutrition Res. Ctr. At Tufts U</td>
</tr>
<tr>
<td>711 Washington Street</td>
</tr>
<tr>
<td>Boston, MA 02111</td>
</tr>
<tr>
<td>Telephone: (617)-556-3200</td>
</tr>
</tbody>
</table>

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 (Site) - See Attached Listing

Report of Animals Used by or Under Control of Research Facility (Attach additional sheets if necessary or use APHIS Form 7023A)

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Animals Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mice</td>
<td>3,363</td>
</tr>
<tr>
<td>Rats</td>
<td>662</td>
</tr>
<tr>
<td>Ferrets</td>
<td>70</td>
</tr>
<tr>
<td>Hamsters</td>
<td>37</td>
</tr>
<tr>
<td>Rabbits</td>
<td>2</td>
</tr>
<tr>
<td>Guinea Pigs</td>
<td>70</td>
</tr>
<tr>
<td>Guinea Pigs</td>
<td>2</td>
</tr>
<tr>
<td>Sheep</td>
<td>37</td>
</tr>
<tr>
<td>Pigs</td>
<td>12</td>
</tr>
<tr>
<td>Sheep</td>
<td>279</td>
</tr>
<tr>
<td>Pigs</td>
<td>191</td>
</tr>
<tr>
<td>Non-Human Primates</td>
<td>3,199</td>
</tr>
<tr>
<td>Other Farm Animals</td>
<td>3,479</td>
</tr>
<tr>
<td>Other Animals</td>
<td>1,479</td>
</tr>
<tr>
<td>Other Animals</td>
<td>279</td>
</tr>
<tr>
<td>Total Number of Animals</td>
<td>4,957</td>
</tr>
</tbody>
</table>

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) The 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 to 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 is 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

Signature: [Signature]

Date Signed: 11-10-03

APHIS Form 7023-A (AUG 91)
Nutritional Immunology Laboratory

October 15, 2001

To: Animal Care and Use Committee, HNRCA
From: Jean Mayer
Re: Category E animals in Amendment to Protocol MS-31

The major limiting factor in conducting our study is the large number of animals needed to collect sufficient number of macrophages for our experiments. This inherent difficulty can be overcome by intraperitoneal injection of thioglycollate (TG) which elicits recruitment of macrophages to peritoneal cavity. TG is a widely used stimulatory agent which induces non-infectious acute peritoneal inflammation in mice and rats. Administration of TG has been shown to increase the total number of macrophages up to four-fold, which will reduce the number of animals necessary for addressing our specific aims.

A number of recent studies have successfully demonstrated that TG-elicited macrophages can be used in the study of some gene expression and signal transduction. However, the feasibility of using TG-elicited macrophages to study COX-2 gene expression is not known.

To test this, we need to inject TG intraperitoneally to mice three days before they are euthanized by CO₂ asphyxiation for macrophage collection. Peritoneal injection will cause discomfort and moderate pain in mice, which unfortunately can not be alleviated. Thus we have classified the animals under category E.
To: Animal Care and Use Committee

From: PI of WA-1 Protocol

RE: Justification of Category E in WA-1 Protocol: Effects of Combined Chemopreventive Agents (9-cis retinoic acid, celecoxib, and 1,25(OH)2 vitamin D3) Against NNK-induced Lung Carcinogenesis in AJ Mice

Protocol WA-1 will include USDA Category E research in which some experimental animal groups will experience pain and/or distress without alleviation. This letter will verify a lack of alternative methods and assure the committee that the proposed research does not unnecessarily duplicate previous experiments.

We propose to conduct an in vivo intervention study to investigate the effectiveness of 9-cis retinoic acid, 1,25(OH)2 vitamin D3, and a COX-2 inhibitor drug alone and in combination as anti-carcinogenic agents in the AJ mouse model of lung cancer. Lung tumors in strain AJ mice resemble human lung adenocarcinoma and have become the preferred test system to study this form of cancer. The target of chemoprevention is premalignant lung disease, making animal models essential for evaluating the efficacy of compounds and interactions in the suppression of tumor progression. Because symptoms rarely occur in the early stages of human lung cancer and many of these early cancers go undiagnosed, mice genetically predisposed to this form of cancer allow us to study lung cancer chemoprevention over the course of months and with fewer animals than similar studies with human subjects. The induction of lung tumors in AJ mice progresses through several distinct stages similar to the stages of human lung cancer. In both mice and humans, adenocarcinomas progress to adenomas and ultimately carcinomas. Further, tumor initiation by a tobacco-derived carcinogen, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), in AJ mice is characterized by premalignant lesions containing a gene alteration that is also present in some human cancers. This makes the AJ mouse an ideal model in which to study lung cancer chemopreventative agents that may be of benefit to the human population. Although we cannot alleviate tumor formation in the NNK-injected control group, the treatment group using combined chemopreventive agents should alleviate tumor formation/distress/animal pain.

While mechanistic hypotheses and data from cellular studies suggest that combinations of vitamins and anti-inflammatory drugs may be effective in lung cancer chemoprevention, there is a clear lack of in vivo work in this area. This will be the first study to examine vitamin A and vitamin D interactions in an animal model of lung cancer and the first study to combine these vitamins with a COX-2 inhibitor to examine synergistic effects. If successful, this study could lead to new approaches in cancer chemoprevention, utilizing combinations of chemopreventive vitamins and drugs in smaller and less toxic doses, thereby avoiding the side effects commonly seen in early clinical trials testing single agents. This research cannot be done using cell models as results cannot be applied to in vivo tumorigenesis.
TO: The HNRC Animal Care and Use Committee  
FROM: NEPS Laboratory  
RE: Justification of Category E in protocol RO-17, “Roles of TNF and interleukin-1 in stress-induced cachexia: Effects of age in transgenic mice”

Our protocol RO-17 addresses the question of whether the cytokines involved in cachexia are the same as sarcopenia (namely TNF, IL-1, and IL-6). This line of research pertains to the mission of the NEPS laboratory, i.e., the understanding and alleviation of physiological or pathological processes leading to sarcopenia, wasting and cachexia.

In RO-17, turpentine will be delivered subcutaneously in one of the hind limbs of wild type and IGF-I transgenic mice. Unfortunately, turpentine injection, although not lethal, results in a sterile abscess that cause pain. This pain is comparable to that felt by humans with a thigh abscess. We anticipate the abscess to be maximal 16 days after injection, and to gradually shrink thereafter. Unfortunately, the pain will not be alleviated by pain killers, as these drugs may induce changes in the levels of muscle cytokines, one of the major endpoints of this study. Because sub-clinical inflammation is a recognized feature of human aging, the proposed experiments are germane to the issue of age-related changes in protein catabolism, inflammation, and immune responses.
Jean Mayer  
United States Department of Agriculture  
Human Nutrition Research Center on Aging  
At Tufts University  

November 10, 2003  

Elizabeth Goldentyer, D.V.M.  
Regional Director - Animal Care  
APHIS, Eastern Regional Office  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5213  
Reference: USDA Annual Report (Registration No.: 14-F-0009)  

Dear Dr. Goldentyer:  

The enclosed documents represent the U.S.D.A. Human Nutrition Research Center on Aging at Tufts University's (HNRCA) "Annual Report of Research Facilities" for the Federal fiscal year, October 1, 2002 through September 30, 2003. Aspects of this report that require comment are:  

1) Animals reported under Category E:  

   a) Mild non-infectious peritoneal inflammation was induced in sixty-one (61) mice by the intraperitoneal injection of thioglycollate to increase the total number of peritoneal macrophages available (which reduced the number of animals used) for peritoneal macrophage harvest. The letter of justification for category E research was submitted with the IACUC animal protocol and is attached.  

   b) Lung tumors were induced in one hundred one (101) mice to examine the combined synergistic effects of vitamin A, vitamin D and COX-2 inhibitors to evaluate their role in lung cancer chemoprevention. The letter of justification for category E research was submitted with the IACUC animal protocol and is attached.  

   c) Sarcopenia was induced in one hundred fifteen (115) mice by the subcutaneous injection of sterile turpentine into the hind limbs of the mice to evaluate if the cytokines involved in cachexia are the same as those of sarcopenia (namely TNF, IL-1 and IL-6) in an effort to understand and potentially alleviate the physiological or pathological processes leading to sarcopenia, wasting and cachexia. The letter of justification for category E research was submitted with the IACUC animal protocol and is attached.  

Should you have any questions regarding the report, please do not hesitate to contact me.

711 Washington Street  
Boston, Massachusetts 02111  
FAX: (617) 556-3344
**ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)**

1. **REGISTRATION NO.**
   B4-P-0001

2. **LOCATION NAME & ADDRESS**
   USDA, APHIS, WS, NWRC
   4101 LAPORTE AVE.
   FT. COLLINS, CO 80521

3. **FACILITY LOCATIONS (Boxed)**

<table>
<thead>
<tr>
<th>A.</th>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experimentation, research, or surgery but not used for such purpose</th>
<th>C. Number of animals upon which teaching, research, experimentation, or tests were conducted involving no pain, distress, or use of pain-relieving drugs</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving some pain or distress to the animals and for which appropriate analgesics, anesthetics, or tranquilizing drugs were used</th>
<th>E. Number of animals upon which teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate analgesics, anesthetics, or tranquilizing drugs were used</th>
<th>F. TOTAL NO. OF ANIMALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>Dogs</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5.</td>
<td>Cats</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Guinea Pigs</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>7.</td>
<td>Hamsters</td>
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<td></td>
</tr>
<tr>
<td>8.</td>
<td>Rabbits</td>
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<td>34</td>
<td>0</td>
<td>0</td>
<td>34</td>
</tr>
<tr>
<td>9.</td>
<td>Non-human Primates</td>
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<tr>
<td>10.</td>
<td>Sheep</td>
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<td></td>
</tr>
<tr>
<td>11.</td>
<td>Pigs</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>12.</td>
<td>Other Farm Animals</td>
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<tr>
<td>13.</td>
<td>Other Animals</td>
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<td>128</td>
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<td>Norway Rats</td>
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<td>0</td>
<td>0</td>
<td>7</td>
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<tr>
<td>Deer Mice</td>
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<td>18</td>
<td>24</td>
<td>0</td>
<td>0</td>
<td>24</td>
</tr>
</tbody>
</table>

**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, teaching, testing, or surgery, or experimentation were followed by the research facility.

2. Each principal investigator has considered alternatives to painful procedures.

3. The 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 approved by the 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**

*Signature of CEO or Institutional Official*

*Date Signed: 10/29/04*

APHIS FORM 7023

*(Replaces US Form 16-28 (Oct 88), which is obsolete)*

*NOV - 7 00*
## Report of Animals Used by or Under Control of Research Facility

### Animals Covered by the Animal Welfare Regulations

<table>
<thead>
<tr>
<th>Animal</th>
<th>Numbers of Animals Used</th>
<th>Number of Animals Used for Pain Requiring Anesthesia or Analgesia</th>
<th>Number of Animals Used for Pain Requiring Analgesia Only</th>
<th>Number of Animals Subjected to a Procedure That Could Cause Them Injury or Death</th>
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<tbody>
<tr>
<td>Ground Squirrels</td>
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<tr>
<td>Fox Squirrels</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skunks</td>
<td>33</td>
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<tr>
<td>Raccoons</td>
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<td></td>
<td></td>
<td></td>
</tr>
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<tr>
<td>Stream Beaver</td>
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<td>0</td>
<td></td>
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<tr>
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<tr>
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<td>Pocket Gophers</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mongoose</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Assurance Statements

1. Professional, acceptable standards governing the care, treatment, and use of animals including approximate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by the 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 approved by the 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, the summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4. The standing veterinarian for this research facility has appropriate authority to assure 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)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

**Signature of CEO or Institutional Official**

<table>
<thead>
<tr>
<th>Name &amp; Title of CEO or Institutional Official</th>
<th>Date Signed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10/23/04</td>
</tr>
</tbody>
</table>

APHIS FORM 7023A

(AUG 01)

NOV - 4 2004
Column E Explanation

1. Registration Number:

2. Number of animals used in this study: 35

3. Species (common name) of animals used in study: *Canis latrans* (coyote)

4. Explain procedure producing pain and/or distress:

   Animals were fed or gavaged with suspensions containing mixtures of caffeine and theobromine to evaluate the potential of these substances as selective predators. Dose vs. Response (percent mortality) curves for three mixtures (13:1 (theo:caf), 5:1 (theo:caf), 100% theo) are being constructed from the toxicity testing data.

5. Provide justification why pain or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results.

   QA-1064 "Development of a Natural, Safe and Effective Plant Based Predator Toxicant" was designed to evaluate the potential of methylxanthines (theobromine, caffeine) as a selective predator toxicant. With experimental toxicants, it is difficult to predict pain or distress experienced by the animals dosed. Administration of other substances (analgesics, etc.) prior to symptoms of intoxication might confound the pharmacological action of the methylxanthine test substances and lead to erroneous conclusions and ideally would be avoided until necessary. Although listed as a Category E study, the protocol permitted the attending veterinarian to administer analgesics, anesthetics and/or euthanasia in instances where the animals were determined to be in pain or distress.

6. What, if any federal regulations require this procedure?

   Agency: none  
   CFR: none
Several attempts have been made to reduce damage by decreasing mountain beaver (*Aplodontia rufa*) populations through the use of conibear-traps. This type of lethal control is becoming politically less popular, as indicated by the passage of Initiative 713 in 2000 (RCW 77.15 section 3) which banned the use of all body gripping traps in the state of Washington. Therefore, alternative tools to conibear traps for reducing mountain beaver populations may be desirable. At present there are no toxicant registered for use to control mountain beaver. A previous study (QA-885) showed that chlorophacinone was the only underground bait that was 100% effective and readily consumed by mountain beaver. LiphaTech currently holds a chlorophacinone label in the form of paraffinized pellets. These pellets are delivered in bags to prevent weather damage. Another recent study (QA 1072) conducted in the Olympia Field Station habitat pens, showed that mountain beaver cached bags. Using LiphaTech’s delivery system might reduce primary hazards as mountain beaver can cache baits inside their nests.

Ten mountain beaver served as subjects. Animals were given a minimum of 2-4 weeks to adapt to pen and burrow system. After adaptation period was over, the bait was placed in a trash can (76 l) in each of the pens. Each container has a 10cm diameter hole at the bottom to allow access and to mimic the rodent’s natural burrow system. Five of the animals received a 12 oz bag of 0.005% chlorophacinone, while the other 5 animals were used as control and given no bait only bags with plain oats. Bait formulation for each treatment was presented as paraffinized pellets. The status of animals was monitored at 2-hour intervals for the first 6 hours, then again every 24 hour for the next 28 days. As administering sedatives or analgesics could affect the toxicity of the chlorophacinone baits, no drugs were administered until acute toxicity was imminent. Animals were frequently monitored to minimize any potential suffering until the completion of the study. Any animal that demonstrated severe symptoms (e.g., convulsions, comatose) of poisoning were euthanatized immediately.

This is a preliminary study to determine if the LiphaTech product might be applicable to a field application. EPA regulations require that for final registration of a product that 70% efficacy with death as an end point be demonstrated. Since this data will support registration we therefore followed EPA regulations with a few modifications to account for a different species (Standard rat anticoagulant place pack dry bait laboratory methods, Guideline #1.217).
Locations where animals in this report were used and/or housed:

USDA, APHIS, WS, NWRC
4101 LaPorte Avenue
Fort Collins, CO 80521

USDA, APHIS, WS, NWRC
Olympia Field Station
9730-B Lathrop Industrial Drive SW
Olympia, WA 98512

USDA, APHIS, WS, NWRC
Logan Field Station
4200 S 600 E
Cache County Road
Millville, UT 84326

USDA, APHIS, WS, NWRC
Hawaii Field Station
PO Box 10880
Hilo, HI 96721
ANNUAL REPORT OF RESEARCH FACILITY

TYPE OR PRINT

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FACILITY LOCATIONS (Sites)

531 VA Medical Center
500 West Fort Street
Boise, ID 83702

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 animals 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 and 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 which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)

F. TOTAL NO. OF ANIMALS

(Cols. C + D + E)

4. Dogs

5. Cats

6. Guinea Pigs

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, teaching, testing, surgery, or experimentation were followed by this research facility.

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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

(Certify that the above is true, correct, and complete (7 USC Section 2143))

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

DATE SIGNED

10/27/03

APHIS FORM 7023 (Replaces VS Form 18-23 (OCT 88), which is obsolete)

(AUG 91)
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 2146.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
   82-Y-001

2. HEADQUARTERS RESEARCH FACILITY (Name and Address as registered with USDA, include Zip Code)
   Department of Veterans Affairs
   VACO
   610 Vermont Avenue NW
   Washington, DC 20420

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)
   S31 VA Medical Center
   600 West Fort Street
   Boise, ID 83702

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 animals 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 suffering, pain, distress, or use of pain-relieving drugs | E | Number of animals upon which teaching, research, experiments, or tests were conducted involving suffering, pain, distress, or use of pain-relieving drugs | F | TOTAL NO. OF ANIMALS |
|---|-----------------------------------|---|----------------------------------------------------------|---|---------------------------------------------------------------------------------|---|-----------------------------------------------------------------|---|--------------------------------------------------|
| 4. | Dogs | | | | | | | | |
| 5. | Cats | | | | | | | | |
| 6. | Guinea Pigs | | | | | | | | |
| 7. | Hamsters | | | | | | | | |
| 8. | Rabbits | 23 | 17 | 1 | 18 | | | | |
| 9. | Non-human Primates | | | | | | | | |
| 10. | Sheep | | 35 | | 35 | | | | |
| 11. | Pigs | | | | | | | | |
| 12. | Other Farm Animals | | | | | | | | |
| 13. | Other Animals | | | | | | | | |
| 14. | Rats | 12 | 13 | 72 | 96 | | | | |
| 15. | Mice | | 22 | | 76 | | | | |

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, 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 approved by the 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)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) DATE SIGNED

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete)

(AUG 91)

DEC 13 2004
Investigator: 

Protocol #: OLS-0014B

Justification of Category E Animals

The category E rabbits were injected with anthracyclines chronically and they may develop congestive heart failure over a 10-week period. Use of anxiolytic agents or stress reducing drugs such as barbiturates or benzodiazepenes may induce or inhibit microsomal liver metabolism or displace anthracyclines from plasma protein stores thereby altering the pharmacokinetics of anthracyclines. Such an effect may interfere with the experimental outcome. The drugs may have direct effects on the proteins of the heart being studied and interfere with the results of the study.
### UNITED STATES DEPARTMENT OF AGRICULTURE
### ANIMAL AND PLANT HEALTH INSPECTION SERVICE

#### ANNUAL REPORT OF RESEARCH FACILITY

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>E. Number of animals upon which teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.</th>
<th>F. TOTAL NO. OF ANIMALS (Cols. C + D + E)</th>
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<tr>
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<td>9. Non-human Primates</td>
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#### 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, 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 approved by the 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)  

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

**Signature of C.E.O. or Institutional Official**  
**Name & Title of C.E.O. or Institutional Official (Type or Print)**  
**DATE SIGNED**  

11/10/04

APHIS FORM 7023 (Replaces VS Form 18-23 (OCT 88), which is obsolete)
Investigator:

Protocol #: OLS-0014B

Justification of Category E Animals

The category E rabbits were injected with anthracyclines chronically and they may develop congestive heart failure over a 10-week period. Use of anxiolytic agents or stress reducing drugs such as barbiturates or benzodiazepines may induce or inhibit microsomal liver metabolism or displace anthracyclines from plasma protein stores thereby altering the pharmacokinetics of anthracyclines. Such an effect may interfere with the experimental outcome. The drugs may have direct effects on the proteins of the heart being studied and interfere with the results of the study.

1 rabbits
Additional information requested for Block E of APHIS Form 7023, dated February 3, 2005

The rabbit involved in this study was injected with anthracyclines or their analogs twice a week for eight weeks. Heart function was assessed by echocardiography. The rabbit was euthanized when fractional shortening was reduced to less than 25% or twenty weeks after the first anthracycline injection. The heart was then removed for further study.
## Annual Report of Research Facility

**Type or Print**

### Registration No.

| Registration No. | 93-V-007 |

### Headquarters Research Facility

**Department of Veterans Affairs**

810 Vermont Ave, N.W.

Washington, DC 20420

---

### Reporting Facility

(Attach additional sheets if necessary)

#### Facility Locations (Sites)

<table>
<thead>
<tr>
<th>Site</th>
<th>Address</th>
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</thead>
<tbody>
<tr>
<td>#600</td>
<td>VA Long Beach Healthcare System 5901 E 7th Street Long Beach, CA 90822</td>
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### Report of Animals Used by or Under Control of Research Facility

(Attach additional sheets if necessary or use APHIS FORM 7023a)

#### Animals Covered by the Animal Welfare Regulations

<table>
<thead>
<tr>
<th>Animals</th>
<th>B. Number of Animals Being Bred, Conditioned, or Held for Use in Teaching, Testing, Experiments, Research, or Surgery but Not Yet Used for Such Purposes</th>
<th>C. Number of Animals upon Which Teaching, Experiments, Research, or Tests Were Conducted Involving Accompanying Pain or Distress, or Use of Pain-Relieving Drugs</th>
<th>D. Number of Animals upon Which Experiments, Teaching, Research, Surgery, or Tests Were Conducted Involving Accompanying Pain or Distress to the Animals and for Which Appropriate Anesthetic, Analgesic, or Tranquilizing Drugs Were Used</th>
<th>E. Number of Animals upon Which Teaching, Experiments, Research, Surgery or Tests Were Conducted Involving Accompanying Pain or Distress to the Animals and for Which Appropriate Anesthetic, Analgesic, or Tranquilizing Drugs Would Have Adversely Affected the Procedures, Results, or Interpretation of the Teaching, Research, Experiments, Surgery, or Tests. (An Explanation of the Procedures Producing Pain or Distress in These Animals and the Reasons Such Drugs Were Not Used Must Be Attached to This Report)</th>
<th>F. TOTAL NO OF ANIMALS</th>
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<tr>
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<td>Pigs</td>
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### 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, 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 approved by the 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)

I certify that the above

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

DATE SIGNED

10/28/23

---

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete)

(AUG 91)

---

Interagency Report Control No. 0180-004-4N
Explanation of Category E:

**Rabbits**

PI: Haake  
Protocols: 0011-178  
04044-02  
Number of animals under Category E: 28  
Procedures involving rabbits fall into Category E because of immunization with adjuvant, which is required for adequate B cell production. Rabbits are sedated with acepromazine 0.25-0.5 mg/kg SC or IM given 10-15 minutes prior to immunization.

PI: Ohning  
Protocol: 01002-03  
Number of animals under Category E: 4  
The reason that procedures involving rabbits fall into category E is because of immunization with adjuvant, which is required for an adequate antibody response. Rabbits are sedated with acepromazine 0.25-0.5 mg/kg SC or IM given 10-15 minutes prior to immunization.

**Rats**

PI: Mayer  
Protocols: 99064-04 (VA project # 0041)  
11091-02 (VA project # 0055)  
Number of animals under Category E: 443  
The rats listed under USDA Category E were subjected to Water Avoidance stress and Colorectal Distension as described in protocols entitled "Modulation of the Pain Response to Repetitive Colorectal Distention" (VA project # 0041), "Influence of choronic water avoidance stress on visceral sensitivity in rats" (VA project # 0055). Water Avoidance causes no harm to the animals, but does cause them discomfort (psychological stress), which is a necessary part of the protocol. Colorectal distension does cause brief pain, however the stimulus is of a very short duration (20 seconds) and is also used in humans. This response cannot be elicited in anesthetized animals. Because the investigator is studying the analgesic effect of different drugs, the use of other analgesics would confound the results and interpretation of the study. None of the rats used during this time interval exhibited signs of excessive or prolonged pain (agitation, vocalization or bleeding during or following testing), which would have necessitated immediate euthanasia.

PI: Sattin/Pekary  
Number of animals under Category E: 25  
25 rats were categorized under Category E for the VA merit review study because the forced swim test is considered psychologically painful. These rats cannot be anesthetized because they would drown during the forced swim test.
A colorectal distention model is used in rats. The study addresses the role of stress and CRF in the genesis and/or maintenance of lower gut motor function alteration and visceral hypersensitivity/pain symptoms. The distention process is unavoidable because the visceral pain response to distention needs to be compared to the response observed after the test substance administration. Because anesthesia will block the abdominal contraction response to distention and because the effect of potential analgesics is studied, the use of anesthesia or other analgesics will confound the data and their interpretation. Thus the pain response to colorectal distention is studied without prior analgesia.

The rats were placed in Category E because they undergo a period of seizures which are not treated during that time. While humans who have had similar seizures do not report pain there may be some distress. The rats are not treated during the seizure period because it is the mechanism of brain damage due to untreated seizures which is being studied in order to develop better treatment.

The rats were used to study the effect of energy deficiency on brain neuronal activation. The rats were fasted for 48 hours and then were euthanized.

Procedures involving 24 mice fall into Category E because of immunization with adjuvant, which is required for adequate B cell production.

The mice listed under Category E were subjected to chemical stimulation of the colon as described in protocol entitled "Modulation of stress-induced pain response in mice" (VA project # 0052). The end point of the chemical stimulation of the colon is significant pain
and discomfort that cannot be alleviated by analgesic since the aim of the study is to investigate pain behavior.

PI: Pandol
Protocols: 0111-42
01008-02
Number of animals under Category E: 40
40 mice are listed under Category E for Protocols # 0111-042 and # 01008-02. In the mouse model of experimental pancreatitis (#0111-042), high doses of cerulein (an analogue of CCK), given as intraperitoneal hourly injections, cause acute pancreatitis. In Protocol # 01008-02 the animals receive either intraperitoneal injections of cerulein or vehicle every hour for 7 hours.
# ANNUAL REPORT OF RESEARCH FACILITY

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

<table>
<thead>
<tr>
<th>Animals Covered by The Animal Welfare Regulations</th>
<th>Number of Animals in 2003</th>
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<td>Hamsters</td>
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<td>Rabbits</td>
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<td>Non-human Primates</td>
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<tr>
<td>Sheep</td>
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<tr>
<td>Pigs</td>
<td></td>
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<tr>
<td>Other Farm Animals</td>
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<td>Other Animals</td>
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**TOTAL NO. OF ANIMALS**

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<th>(Cols. C + D + E)</th>
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### ASSURANCE STATEMENTS

1. Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquillizing drugs, prior to, during, and following actual research, testing, teaching, surgery, or experimentation were followed by the research facility.

2. Each principal investigator has considered alternatives to painful procedures ( ) indicates number reported in 2003 and continued in 2004.

3. This facility is adhering to the standards and regulations under the Act, and it has required that no animals be used that are painful or distressing to the animals and that procedures or experiments or testing be performed in which the use of appropriate anesthetic, analgesic, or tranquillizing drugs would have adversely affected the procedures, results, or interpretation of the research.

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)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

**SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL**

**DATE SIGNED**

**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL**

**SPACE FOR ADDITIONAL INFORMATION**

**INTERAGENCY REPORT CONTROL No.**

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**APHIS FORM 7023**

(Replaces VS FORM 18-23 (OCT 88), which is obsolete)

**PART 1 - HEADQUARTERS**

**(AUG 91)**
ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 86-R-0031
   CUSTOMER NUMBER: 1688

Sun Health Research Institute
10515 W. Santa Fe Dr.
Sun City, AZ 85351
Telephone: (623) -876-5328

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 7022A)

<table>
<thead>
<tr>
<th>Category</th>
<th>A. Number of animals used for purposes</th>
<th>B. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving pain, distress, or use of pain-relieving drugs</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress in the animals and for which appropriate analgesic, anesthetic, or tranquilizing drugs were used</th>
<th>E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress in the animals and for which appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in such animals and the reasons such drugs were not used must be attached to this report)</th>
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<tbody>
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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 teaching, research, 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 be specified and explained by the principal investigator and as 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 in 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)

NAME & TITLE OF O.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED: 11/23/04

APHIS FORM 7022 (Replaces VS FORM 7022A, which is obsolete.)

NOV 29 2004
**Continuation Sheet for Annual Report of Research Facility**

**United States Department of Agriculture**
**Animal and Plant Health Inspection Service**

**FY 2004**

**CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY**

**TYPE OR PRINT**

---

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY**

(Attach additional sheets if necessary or use APMIS Form 7223-A)

<table>
<thead>
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<th>A. Animals Covered By the Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research or surgery but not yet used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments or tests were conducted involving no pain, distress or use of pain-relieving drugs</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery or tests were conducted involving discomfort or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
<th>E. Number of animals upon which teaching, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic or tranquilizing drugs were used</th>
<th>F. TOTAL NO. OF ANIMALS (Col. C + D + E)</th>
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<td>0</td>
</tr>
<tr>
<td>Fish</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other Amphibians</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Vole</td>
<td>9</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>Mink</td>
<td>0</td>
<td>85</td>
<td>0</td>
<td>0</td>
<td>85</td>
</tr>
<tr>
<td>Wild Mice</td>
<td>29</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Llamas</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Chinchillas</td>
<td>0</td>
<td>0</td>
<td>29</td>
<td>0</td>
<td>29</td>
</tr>
</tbody>
</table>

**ASSURANCE STATEMENTS**

1) Professionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetics and tranquilizing drugs prior to, during and following usual research, 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 approved by the 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)

Signature of C.E.O. or Institutional Official

Name and Title of C.E.O. or Institutional Official (Type or print)

Date Signed: 11/28/07

APRIS Form 7223A

(AUG 97)
UNIVERSITY DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 84-R-0040
   CUSTOMER NO. 1097
   FORM APPROVED OMB NO. 0579-0038
   Interagency Report Control No 0150-D044-A00

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA; include Zip Code)
   INHAUSEN RESEARCH INSTITUTE, INC.
   PMB 5065/2016 S. LEMAY AVE., SUITE 7
   FORT COLLINS, CO 80525
   (970) 221-1080

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)
   FACILITY LOCATIONS (sites)
   2625 Midpoint Dr., Ft. Collins, CO 80525
   2619 Midpoint Dr., Ft. Collins, CO 80525
   2637 Midpoint Dr., Ft. Collins, CO 80525

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 72034)

<table>
<thead>
<tr>
<th>A. Animals Covered by The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
<th>E. Number of animals upon which teaching, experiments, research, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
<th>F. TOTAL NO. OF ANIMALS (Cols. C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td>48</td>
<td>230</td>
<td>34</td>
<td>54</td>
<td>318</td>
</tr>
<tr>
<td>5. Cats</td>
<td>0</td>
<td>45</td>
<td>0</td>
<td>0</td>
<td>45</td>
</tr>
<tr>
<td>6. Guinea Pigs</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>7. Hamsters</td>
<td>0</td>
<td>116</td>
<td>0</td>
<td>0</td>
<td>116</td>
</tr>
<tr>
<td>8. Rabbits</td>
<td>0</td>
<td>108</td>
<td>6</td>
<td>0</td>
<td>114</td>
</tr>
<tr>
<td>9. Non-Human Primates</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10. Sheep</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>11. Pigs</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>12. Other Farm Animals</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13. Other Animals</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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, teaching, 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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the 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)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL
(Replaces VII 16.83 (Out 59), which is obsolete)

APHIS
(AU)

DATE SIGNED

PART 1 - HEADQUARTERS

OCT 30 2005
Registration Number: 84-R-0040
Number of animals used in this study: 23
Species of animal in this study: Dog
Explanation of the procedure producing pain and/or distress:
A long lasting analgesic to be used in dogs is tested for efficacy using a surgical model. Female dogs received an ovariohysterectomy (spay). Surgeries were performed under general anesthetic. There are no alternatives to testing analgesics in the target animal. It is common for client owned animals that undergo surgery in clinical practices not to receive analgesics. In one study, 52% of male veterinarians and 36% of female veterinarians did not routinely administer any type of analgesia pre or post operatively to ovariohysterectomy patients and 32% of males and 24% of females did not administer analgesia to animals undergoing abdominal surgery other than ovariohysterectomy. In this study dogs that underwent abdominal surgery were placed in one of four groups. One group of animals received carprofen (a common post operative analgesic) according to package directions starting immediately prior to surgery. Two groups of dogs were given the test article (a novel analgesic) immediately prior to surgery. Each group received a different dose of test article. It is necessary to include a control group that did not receive any analgesics to establish the efficacy of the novel analgesic. If there was a failure to differentiate between treated groups, it could be attributed to a true lack of difference between treatments, or an insensitivity of the pain assessment scales. The inclusion of untreated controls will help differentiate any effects seen in the animals. All animals were evaluated frequently for pain levels, both by physical exams and by video monitoring. Any animal that may have received a pain score above acceptable level would receive morphine to alleviate the pain. This was done regardless of which group the animal was in.
Column E Explanation

Registration Number: 84-R-0040
Number of animals used in this study: 26
Species of animal in this study: Dog
Explanation of the procedure producing pain and/or distress:
These dogs were used to test the treatment of oral or topical treatments for flea allergic dermatitis (FAD). There were several groups which included animals treated with currently accepted treatments for FAD as well as experimental treatments and placebo control animals. It is necessary to use the host species for this type of study as there are no non animal models of the integrated immune and inflammatory function of a live animal. Untreated control animals are also necessary to determine the effect of the different test groups with the untreated animals. Dogs which have been sensitized to fleas were used by placing 20 fleas between the shoulder blades of each dog and allowing the fleas to burrow into the hair. The amount of reaction to the fleas was determined by frequent physical exam. Any animals, regardless of group, which developed excessive clinical signs caused by the fleas, such as open sores which require treatment with antibiotics, were treated immediately with appropriate insecticides to eliminate the flea infestation. The animal would also receive any other appropriate treatment necessary to eliminate clinical signs of FAD.
### CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

#### TYPE OR PRINT

<table>
<thead>
<tr>
<th>Permit of Animal Use by or Under Control of Research Facility (Enter Date) (See IAR Form 387-006)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. REGISTRATION: 74-R-0046</td>
</tr>
<tr>
<td>Form APPROVED:</td>
</tr>
<tr>
<td>OMB No. 0570-0069</td>
</tr>
</tbody>
</table>

#### HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA) (Include ZIP Code)

Southwest Texas State University
601 University Drive
San Marcos, TX 78666

#### PERMIT OF ANIMAL USE BY OR UNDER CONTROL OF RESEARCH FACILITY (Enter Date) (See IAR Form 387-006)

<table>
<thead>
<tr>
<th>Animal Category</th>
<th>Number on List</th>
<th>Number on Permit</th>
<th>Number Under Use</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>bats</td>
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<td>0</td>
<td>63</td>
<td>63</td>
</tr>
<tr>
<td>various mammals</td>
<td>0</td>
<td>10</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>birds</td>
<td>0</td>
<td>0</td>
<td>40</td>
<td>40</td>
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<td>0</td>
<td>800</td>
</tr>
<tr>
<td>fish</td>
<td>30</td>
<td>30</td>
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</tr>
<tr>
<td>fish</td>
<td>40</td>
<td>160</td>
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<tr>
<td>nsn</td>
<td>55</td>
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<td>35</td>
<td>35</td>
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<td>fish, Xiphophorus</td>
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<td>1900</td>
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<tr>
<td>fish</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>salamanders</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

#### ASSURANCE STATEMENT

1) Individuals responsible for maintaining the care, treatment, and use of animals including veterinarians, technologists, and technical staff personal, in accordance with ethical and humane standards, and the administration of drugs, medications, or other therapeutic measures to prevent pain and distress are responsible for ensuring that all necessary steps are taken to ensure the health and welfare of the animals.

2) Additional information should be provided if necessary.

3) The facility is in compliance with the standards and regulations established by the Institutional Animal Care and Use Committee (IACUC).

4) The facility has received a certificate of compliance from the IACUC.

5) The facility has completed the necessary training and education programs.

#### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

I certify that the above is true, correct, and complete (I.C.C. Section 214).

Signature of CEO or Institutional Official

Name & Title of CEO or Institutional Official (Type or Print)

Date Signed: 12/1/2003
ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

3a. Site 1 - 601 University Dr., San Marcos (main campus)
3b. Site 2 - University Farm, RR12, San Marcos

<table>
<thead>
<tr>
<th>Animal Group</th>
<th>Conditioned</th>
<th>Number of Animals</th>
<th>Number of Animals upon Number of Animals upon</th>
<th>Number of Animals upon Number of Animals upon</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td>0</td>
<td>0</td>
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<td>0</td>
</tr>
<tr>
<td>5. Cats</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6. Guinea Pigs</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>7. Hamsters</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>8. Rabbits</td>
<td>0</td>
<td>0</td>
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<td>0</td>
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<tr>
<td>9. Non-human Primates</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10. Sheep</td>
<td>42</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>11. Pigs</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12. Other Farm Animals</td>
<td>215 cows</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>20 goats</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13. Other Animals</td>
<td>4300</td>
<td>3178</td>
<td>5103</td>
<td>56</td>
</tr>
</tbody>
</table>

ACCURACY STATEMENTS

1) Pretrial and postmortem examinations are conducted on all animals upon their arrival, upon their death, and at the end of the study, surgery, and any experimentation that was performed on the animals.

2) Each research investigator has been trained in the handling and care of animals.

3) This facility is subject to the requirements of the Animal Welfare Act and its implementing regulations.

4) The facility has a licensed veterinarian on staff to oversee the health and welfare of the animals.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

Signature of CEO or Institutional Official: [Signature]
Signature of Institutional Official: [Signature]
Date: [Date]

DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Southwest Texas State University
601 University Drive, JCK Suite 489
San Marcos, TX 78666
Registration Number: 22-R-0036

November 22, 2003

Elizabeth Goldentyer, DVM
UNITED STATES DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service
Regulatory Enforcement and Animal Care
Eastern Region Office
920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Dear Dr. Goldentyer:

Listed below are comments to accompany the annual report of research facilities for site number 1.

The environmental enrichment program has exceptions for social housing for nonhuman primates. Twenty-three rhesus monkeys are housed separately due to special study requirements for controlling and monitoring food consumption as part of the research projects. Twenty cynomolgus monkeys were housed separately for brief periods (1-2 days) while participating in telemetric monitoring studies. All the animals are included in all the other aspects of the environmental enrichment program. The protocols with the exemption are approved by the IACUC and reviewed during the semi-annual program review.

One exception to the canine exercise program is to be reported and involved eight animals. It involved the use of special canine metabolism cages for drug metabolism studies or urine collection studies. The canine metabolism cages provide greater than 100%, but less than 200% of required space for exercise. The period of time in the cages vary with the test compound and study. Most of the studies lasted for 24 hours and the longest lasted for 42 days. Positive human interaction is greatly increased during this period. The protocols with the exemption are approved by the IACUC and reviewed during the semi-annual program review.

Listed below are comments to accompany the annual report of research facilities for site Number 2.

A. Summary of exceptions to the regulations and standards:

There were some exemptions to the pair-housing requirement of our IACUC approved program for the psychological well-being of non-human primates. Most exemptions were for approximately two weeks in duration. A total of five hundred and forty-four non-human primates were exempted from social housing for reasons which include: acclimation and health assessment during the beginning of the quarantine period, establishing suitable cage mates and preparing social caging.
# Annual Report of Research Facility

**University of Missouri-Columbia**

**205 Jesse Hall**

**Telephone:**

(573)882-9500

**Columbia, MO 65211**

## Report of Animals Used by or Under Control of Research Facility

### A. Animals Covered by the Animal Welfare Regulations

<table>
<thead>
<tr>
<th>Animals Covered by The Animal Welfare Regulations</th>
<th>Number of animals being bred, conditioned, or held for use in teaching, testing, experimentation, research, or surgery that are not yet used for such purposes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
<td>50</td>
</tr>
<tr>
<td>Cats</td>
<td>2</td>
</tr>
<tr>
<td>Guinea Pigs</td>
<td>1</td>
</tr>
<tr>
<td>Hamsters</td>
<td>0</td>
</tr>
<tr>
<td>Rabbits</td>
<td>15</td>
</tr>
<tr>
<td>Non-human Primates</td>
<td>0</td>
</tr>
<tr>
<td>Sheep</td>
<td>2</td>
</tr>
<tr>
<td>Pigs</td>
<td>579</td>
</tr>
<tr>
<td>Other Farm Animals</td>
<td>0</td>
</tr>
<tr>
<td>Horses</td>
<td>10</td>
</tr>
<tr>
<td>Bats</td>
<td>8</td>
</tr>
<tr>
<td>Opossum</td>
<td>0</td>
</tr>
<tr>
<td>Wild mice</td>
<td>0</td>
</tr>
</tbody>
</table>

### B. Number of animals upon which teaching, research, experiments, or tests were conducted involving pain or distress to the animals and for which the use of appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedure, results, or interpretation of the teaching, research, experimentation, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)

| B. Number of animals upon which teaching, research, experiments, or tests were conducted involving pain or distress to the animals and for which the use of appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedure, results, or interpretation of the teaching, research, experimentation, surgery, or tests. | 0 |

### C. Number of animals upon which teaching, research, experiments, or tests were conducted involving pain or distress to the animals and for which the use of appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedure, results, or interpretation of the teaching, research, experimentation, surgery, or tests.

| C. Number of animals upon which teaching, research, experiments, or tests were conducted involving pain or distress to the animals and for which the use of appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedure, results, or interpretation of the teaching, research, experimentation, surgery, or tests. | 284 |

### D. Number of animals upon which teaching, research, experiments, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedure, results, or interpretation of the teaching, research, experimentation, surgery, or tests.

| D. Number of animals upon which teaching, research, experiments, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedure, results, or interpretation of the teaching, research, experimentation, surgery, or tests. | 0 |

### E. Number of animals upon which experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedure, results, or interpretation of the teaching, research, experimentation, surgery, or tests.

| E. Number of animals upon which experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate analgesic, anesthetic, or tranquilizing drugs would have adversely affected the procedure, results, or interpretation of the teaching, research, experimentation, surgery, or tests. | 0 |

### F. Total Number of Animals

| Total Number of Animals (Column C + D + E) | 315 |

---

### Assurance Statements

1. Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetics, analgesics, and tranquilizing drugs, prior to, during, and following animal research, testing, and surgery, were followed through the conduct of 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 reviewed all exceptions to the standards and regulations to ensure that no exceptions are taken.

4. This facility is adhering to the standards and regulations under the Act, and it has reviewed all exceptions to the standards and regulations to ensure that no exceptions are taken. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)

---

**Certification by Headquarters Research Facility Official**

(Chief Executive Officer of Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete. (7 U.S.C. Section 1943)

Name & Title of D.O.I or Institutional Official

Date Signed:

11/20/00

---

**PMR FORM 7023A**

11/20/00
CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

1. REGISTRATION NO. 43-R-0048

2. HEADQUARTERS RESEARCH FACILITY (Name and Address as registered with USDA) Include Zip Code
   University of Missouri-Columbia
   205 Jesse Hall
   Columbia, MO 65211

| Animals Covered By The Animal Welfare Regulations | B. Number of animals 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 experiments, teaching, research, surgery, 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 pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report. | E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs were used, or which were permitted according to the Animal Welfare Act. | F. TOTAL NO. OF ANIMALS
   (Cols. C - D - E) |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>12. &amp; OR 13. Other (List by species)</td>
<td>70</td>
<td>0</td>
<td>270</td>
<td>0</td>
<td>270</td>
</tr>
<tr>
<td>gerbils</td>
<td>0</td>
<td>50</td>
<td>0</td>
<td>0</td>
<td>50</td>
</tr>
<tr>
<td>voles</td>
<td>0</td>
<td>50</td>
<td>0</td>
<td>0</td>
<td>50</td>
</tr>
</tbody>
</table>

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, 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 approved by the 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
(Cabinet Officer or Legally Responsible Institutional Official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

<table>
<thead>
<tr>
<th>NAME &amp; TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL</th>
<th>DATE SIGNED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11/20/00</td>
</tr>
</tbody>
</table>
University of Missouri-Columbia (43-R-048)
Annual Report of Research Facility - Attachments

CLINIC LOCATIONS:

Allison Bldg.
- lab: room 233, 234

Animal Science Research Center
- animal housing facility: ASRC Units B, C, D, F,
- labs: E142, N126, N152, N153, & N190

Clydesdale Hall
- animal housing facility: 13, A222 ward, A227, A230-1, A253, A256, A258, A273, B120C, B125, B206, B213, & B229

Connaway Hall
- animal housing facility, 1st floor: rooms W2-23, W104, W117, and W102-W123

Dalton Research Center
- labs: 104, 203, 209, 229, 306, 309, 310, 311, 312, 313, 314, 322, 325, 326, 328

Engineering Bldg
- animal housing: room C2204

Green Building
- animal housing: room 115

Laboratory Animal Center
- animal housing facility: rooms 1-26

Leffurve Hall
- animal housing: rooms 2, 3, 5, 9, 19, 21, 24, 27, 28A, 28B, 28C, 28D, 28E, 29A, 29B, 29C, 206,
- labs: 113, 208, 209, 214

Medical Science Building
- centralized animal care facility, 1st floor (including experimental surgery) - animal housing rooms: A101-A164
- labs: rooms M332, M401, M420, M423, M463, M514, M648, N422, N507, NE305, NE306, NW300, and NW303

Dolebush Farm
- animal housing and use: Equine Center, Theriogenology Bldg., paddocks
# ANNUAL REPORT OF RESEARCH FACILITY

- **TYPE OR PRINT**

## FACILITY LOCATIONS (Sites)

<table>
<thead>
<tr>
<th>Site</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA Loma Linda Healthcare System</td>
<td>1201 Benton St., Loma Linda CA 92357</td>
</tr>
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## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cats</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guinea Pigs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hamsters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rabbits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-human Primates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sheep</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pigs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Farm Animals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chinchillas</td>
<td></td>
<td>30</td>
</tr>
</tbody>
</table>

**Correction:** See attached report dated 30 June 04.

## 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, teaching, testing, surgery, or experimentation were followed by this research facility.

2. Each principal investigator has considered alternatives to painful procedures.

3. The facility is adhering to the standards and regulations under the Act, and it has required that exceptions to these standards be specified and explained by the principal investigators and approved by the institutional animal care and use committee (IACUC). A summary of all such exceptions is attached to this annual report.

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)

I certify that the above is true, correct, and complete (7 U.S.C Section 2143)

<table>
<thead>
<tr>
<th>TURE OF C.E.O. OR INSTITUTIONAL OFFICIAL</th>
<th>NAME &amp; TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)</th>
<th>DATE SIGNED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>11/4/03</td>
</tr>
</tbody>
</table>

**TPH FORM 7023** (Replaces VS FORM 18-23 (OCT 88), which obsolete.)

**DATE SIGNED**

**JUL 8 2004**

**PART 1: HEADQUARTERS**
This report is required by law (7 U.S.C. 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 in Section 2143.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
93-Y-004

2. HEADQUARTERS RESEARCH FACILITY (Name and Address as registered with USDA, include Zip Code)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

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

FACILITY LOCATIONS (Sites)
664-VA San Diego Healthcare System
3350 La Jolla Village Drive
San Diego, CA 92161

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

A. Animals Covered By The Animal Welfare Regulations

B. Number of animals 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 animal and for which appropriate anesthesia, 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 which appropriate anesthesia, analgesic, or tranquilizing drugs were used.

F. TOTAL NO. OF ANIMALS (Cats. A + B + D + E)

4. Dogs
0

5. Cats
0

6. Guinea Pigs
0 0 101 0 101

7. Hamsters
0

8. Rabbits
0 3 91 1527 1621

9. Non-human Primates
0

10. Sheep
0

11. Pigs
0

12. Other Farm Animals
0

13. Other Animals
0

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, teaching, 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 been determined that exceptions to the standards and regulations are justified and explained by the principal investigator and approved by the 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 the 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 of Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

APHIS FORM
(AUG '91)

VS FORM 18-23 (OCT 89), which is obsolete

CART 4 HEADQUARTERS
# ANNUAL REPORT OF RESEARCH FACILITY

## TYPE OR PRINT

### 1. REGISTRATION NO.
- 74-R-0049

### CUSTOMER NO.
- 1503

### FORM APPROVED
- OMB NO. 0579-0036

### 2. HEADQUARTERS RESEARCH FACILITY
- Name and Address: STILLMEADOW INC
- 12552 PARK ONE DR
- SUGAR LAND, TX 77478

### 3. REPORTING FACILITY
- Name and Address: SITE:
- SUGAR LAND, TX 77478

### FACILITY LOCATION:

| SITE | SUGAR LAND, TX 77478 |

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

### A. Animals Covered By The Animal Welfare Regulations

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experimenting, research, or surgery but not yet used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
<th>E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were not used but must be attached to this report</th>
<th>F. TOTAL NO. OF ANIMALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td>150</td>
<td>531</td>
<td>8</td>
<td>24</td>
<td>563</td>
</tr>
<tr>
<td>5. Cats</td>
<td>49</td>
<td>155</td>
<td>24</td>
<td>179</td>
<td></td>
</tr>
<tr>
<td>6. Guinea Pigs</td>
<td>541</td>
<td>28</td>
<td>570</td>
<td></td>
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<td>7. Hamsters</td>
<td>86</td>
<td>20</td>
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<tr>
<td>8. Rabbits</td>
<td>1200</td>
<td>140</td>
<td>1340</td>
<td></td>
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<tr>
<td>9. Non-Human Primates</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>10. Sheep</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Pigs</td>
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<td></td>
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<td></td>
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<td>12. Other Farm Animals</td>
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<tr>
<td>Horses</td>
<td>2</td>
<td>11</td>
<td>13</td>
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<td></td>
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<tr>
<td>13. Other Animals</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### ASSURANCE STATEMENTS

1. Professionally acceptable standards governing the care, treatment, and use of animals, including proper 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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the 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) I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

<table>
<thead>
<tr>
<th>SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL</th>
<th>NAME &amp; TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL</th>
<th>DATE SIGNED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>11/21/2003</td>
</tr>
</tbody>
</table>

### APHIS FORM 7032 (AUG 91)

(Replaces VS FORM 15-23 (Oct 81), which is obsolete)

### PART 1 - HEADQUARTERS

APR 7 2004
Justification for response in "E"

** Birds were trapped and fitted with an external radio transmitter and released

*** Animals are killed by the AVMA-Approved method of spinal section and pithing. They presumably experience some distress during capture, and momentary pain during the killing procedure
1. Registration Number: 74-R-0049 / 1503

2/3. Species (common name) & Number of animals used in this study:

<table>
<thead>
<tr>
<th>Dogs (24)</th>
<th>Cats (24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guinea Pigs (29)</td>
<td>Rabbits (140)</td>
</tr>
</tbody>
</table>

4. Explain the procedure producing pain and/or distress.

The pain or distress in dogs in Column E was due to flea allergy dermatitis. These dogs were not treated with anesthetics or analgesics because the particular tests being conducted were efficacy tests of drugs designed to prevent or reduce symptoms of flea allergy dermatitis. Efficacy of these drugs can only be determined if the animals are infested with fleas and exhibit flea allergy dermatitis. The cats referenced in Column E were animals used as flea hosts. It is assumed they suffer stress and discomfort from the flea infestation. When toxicity and/or irritation studies are done on rabbits, test material is either dropped into one eye of the rabbit or it is applied to the skin. When this dosing to the eye occurs, the animals occasionally squeal; and it is assumed that they squeal in pain or distress. Guinea pigs are restrained temporarily during and after administration of the test material in sensitization studies. They find the restraint stressful. In the case of dermal toxicity tests, cage-side observations include evaluation of the central nervous system, somamotor activity and behavior patterns. These would be altered by the use of anesthetics or tranquilizers.

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)

Most studies are federally mandated. However, we sometimes conduct screens to determine if further testing is necessary. When doing these screens, observations are made to the treated areas on rabbits, looking for signs of irritation (usually redness or swelling) that may have been caused by the test material. We do not always use anesthetics because we may not be able to distinguish between discoloration caused by the test material and discoloration possibly caused by an anesthetic.

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):

Agency: USEPA Health Effects Test Guidelines, Office of CFR
Prevention, Pesticides and Toxic Substances, OPPTS
870-1200, Acute Dermal Toxicity, OPPTS 870.2400, Acute Eye Irritation, OPPTS 870-2500, Acute Dermal Irritation, OPPTS 870-2600, Guinea Pig Sensitization

Approval Status:
Approved/Disapproved By:
Date:
Disapproved Reason:
### ANNUAL REPORT OF RESEARCH FACILITY

#### (TYPE OR PRINT)

<table>
<thead>
<tr>
<th>Animal Type</th>
<th>No. Used</th>
<th>No. Under Control</th>
<th>No. Under Care</th>
<th>No. Under Use</th>
<th>No. Under Use for Experiments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
<td>94</td>
<td>151</td>
<td>3</td>
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<tr>
<td>Cats</td>
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</tr>
<tr>
<td>Guinea Pigs</td>
<td>0</td>
<td>2435</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hamsters</td>
<td>0</td>
<td>110</td>
<td>0</td>
<td></td>
<td></td>
</tr>
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<td>Rabbits</td>
<td>0</td>
<td>352</td>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-human Primates</td>
<td>95</td>
<td>470</td>
<td>413</td>
<td>8</td>
<td>891</td>
</tr>
<tr>
<td>Sheep</td>
<td>0</td>
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</tr>
<tr>
<td>Pigs</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Other Farm Animals</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
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<tr>
<td>Other Animals</td>
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<td></td>
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<tr>
<td>Cebils</td>
<td>0</td>
<td>48</td>
<td>4272</td>
<td>0</td>
<td>4320</td>
</tr>
</tbody>
</table>

### ISSUANCE 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 use 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 be approved 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

Name & Title of C.E.O. or Institutional Official: 

Date Signed: 11/25/03

---

This form is required by law (7 USC 2143). Failure to report according to the regulations can result in a fine of up to $100,000. See attached form for additional information.
Customer ID and Site Address: Site 1

ID: 181
2000 Galloping Hill Rd
Kanilworth, NJ 07033
County: Union

Telephone
(908)298-4000
Customer ID and Site Address: Site 2

ID: 181
P O Box 32 Route 94
Lafayette, NJ 07848
County: Sussex

Telephone: (973) 940-4100
ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

FACILITY LOCATIONS (Sites)

671
South Texas Veterans Health Care System
Audie L. Murphy Division
7400 Merton Minter Blvd.
San Antonio, TX 78284

5. Cats

6. Guinea Pigs

7. Hamsters

8. Rabbits

9. Non-human Primates

10. Sheep

11. Pigs

12. Other Farm Animals

13. Other Animals

Rats
Mice

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, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required (a) exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the 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.

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

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

APHIS FORM 7023
(AUG 91)
ANNUAL REPORT OF RESEARCH FACILITY

FACILITY LOCATIONS (Specify)
Boston University Medical Center
Lab Animal Science Center, 700 Albany Street

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

<table>
<thead>
<tr>
<th>Animals Covered</th>
<th>A. Number of animals being bred, conditioned, or held for use in teaching, research, experiments, or surgery but not yet used for such purposes</th>
<th>B. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving pain, distress, or use of pain-relieving drugs</th>
<th>D. Number of animals upon which teaching, research, experiments, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
<th>E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
<th>F. TOTAL NO. OF ANIMALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canines</td>
<td>14</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>Cats</td>
<td>0</td>
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<td>0</td>
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<td>Guinea Pigs</td>
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<td>0</td>
<td>108</td>
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<td>108</td>
</tr>
<tr>
<td>Hamsters</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Rabbits</td>
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<td>178</td>
<td>246</td>
<td>0</td>
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<td>424</td>
</tr>
<tr>
<td>Non-human Primates</td>
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<td>60</td>
<td>0</td>
<td>0</td>
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<td>0</td>
</tr>
<tr>
<td>Pigs</td>
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<td>62</td>
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<td>64</td>
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<tr>
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<tr>
<td>Poikilotherms</td>
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<tr>
<td>Mice</td>
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<td>696</td>
<td>0</td>
<td>0</td>
<td>2,45</td>
</tr>
<tr>
<td>Chinchillas</td>
<td>0</td>
<td>0</td>
<td>220</td>
<td>25</td>
<td>0</td>
<td>245</td>
</tr>
</tbody>
</table>

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, 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 approved by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report.
4) The preceding veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care to 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)
I certify that the above is true, complete, and accurate (7 USC Section 2143)

DATE SIGNED

APHIS FORM 7023
(Replaces US Form 18-33 (Oct 88), which is obsolete)
(AUG 91)
**UNITED STATES DEPARTMENT OF AGRICULTURE**  
**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**ANNUAL REPORT OF RESEARCH FACILITY**  
**TYPE OR PRINT**

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

**FACILITY LOCATIONS (Site)**

| Moore Drive Site: Drug Evaluation Lab | Cornwallis Road Site: Toxicology Animal |

**Drug Safety Assessment**

**Facility, Research Commons II**

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheet if necessary or use APHIS FORM 7024.)**

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of procedures being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.</th>
<th>D. Number of animals upon which teaching, research, experiments, or tests were conducted involving pain, distress, or use of pain-relieving drugs.</th>
<th>E. Number of animals upon which teaching, research, experiments, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetics, analgesics, or tranquilizing drugs were used.</th>
<th><strong>P. TOTAL NO. OF ANIMALS</strong> (Cols. C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td>20</td>
<td>150</td>
<td>4</td>
<td>26</td>
<td>180</td>
</tr>
<tr>
<td>5. Cats</td>
<td>0</td>
<td>1</td>
<td>124</td>
<td>0</td>
<td>125</td>
</tr>
<tr>
<td>6. Guinea Pigs</td>
<td>4</td>
<td>97</td>
<td>2</td>
<td>0</td>
<td>99</td>
</tr>
<tr>
<td>7. Hamsters</td>
<td>0</td>
<td>169</td>
<td>0</td>
<td>0</td>
<td>169</td>
</tr>
<tr>
<td>8. Rabbits</td>
<td>0</td>
<td>82</td>
<td>17</td>
<td>0</td>
<td>99</td>
</tr>
<tr>
<td>9. Non-human Primates</td>
<td>0</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>10. Sheep</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>11. Pigs</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12. Other Farm Animals</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13. Other Animals</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**ASSURANCE STATEMENTS**

1. Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetics, analgesics, and tranquilizing drugs, prior to, during, and following actual research, 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 approved by the 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)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2152).

**SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL**

**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)**

**DATE SIGNED**

**APHIS FORM 7024**

(AUG 91)
USDA Registration Number 55-R-026
Attachment to USDA Annual Report dated November 28, 2000
Explanation of Animals Listed in Column E of this Report

The 26 dogs listed in Column E for this reporting year are assigned to a study that involves transection of the cranial cruciate ligament. The purpose of the study is to create an inflammatory disease model, which will be used to test new compounds developed for the treatment of osteoarthritis. Even though analgesics are administered immediately postoperatively these will be discontinued within 24 hours after the surgery. Administering analgesics may interfere with the disease course because pain level changes are associated with neurological and endocrinological changes that affect the inflammatory process. Administration of test compound begins at 4-7 days post op with dogs being placed in a structured exercise program (pre-acclimated prior to surgery) at 7 days post op.

The Veterinarians and IACUC feel that these dogs potentially experienced “more than slight or momentary pain or distress”, as defined in the Animal Welfare Act. Even though additional analgesics are not provided, the dogs are monitored by the Veterinarian and the scientist for such clinical signs as weight loss, inappetence, inability or unwillingness to use the affected limb, etc. which would be indicative of a need to potentially euthanize a given dog.