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 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 10-F-0002
CUSTOMER NUMBER: 439

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Walter Reed Army Institute Of Research
Div. Of Veterinary Medicine
Building 511 Robert Grant Ave.
Silver Spring, MD 20910

Telephone: (301) -319-7100

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would heve adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	20	136	367	523
7. Hamsters	0	0	67	0	67
8. Rabbits	0	88	117	6	211
9. Non-human Primates	263	387	0	0	387
10. Sheep	0	0	0	0	0
11. Pigs	0	106	280	8	394
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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. OR INSTITUT OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		2004

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 68), which is obsolete.)
(AUG 91)

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 10-F-0002

2. Number 147 of animals used in this study.

3. Species (common name) Guinea Pig of animals used in the study.

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

The guinea pigs will be exposed to subacute or to chronic low-dose Soman, Sarin, or VX. Neurological observations will be performed before, during, and following dosing.

Some nerve agent-exposed guinea pigs will be prepared using biotelemetry techniques for the collection and analysis of EEG, EKG, body temperature, and locomotor acitivity data. Guinea pigs will be anesthetized to achieve deep surgical anesthesia using a solution containing a mixture of Ketamine and Xylazine. Having achieved deep surgical anesthesia, either the surgical procedures or euthanasia will be conducted.

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)

Nerve agent exposed Guinea pigs may experience seizures. The pre- and post-seizure periods may be accomplished by distress. The relief of the pre-seizure period of distress is difficult to predict and pharmacological treatment is contraindicated if we are to determine the primary effects of nerve agent exposure.

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 _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 10-F-0002

2. Number 220 of animals used in this study.

3. Species (common name) Guinea Pig of animals used in the study.

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

Shigella vaccine candidates were evaluated by placing Shigella in the conjuctivae of guinea pigs' eyes, and then the severity of inflammation was scored.

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)

The study of immune response to and protective efficacy of vaccine candidates directed against Shigella requires an accurate evaluation of the immune response raised by the administration of these vaccines. The use of analgesics, particularly opiates or narcotics, result in immunosuppression, which would invalidate the results of experiments testing immune responses as well as increasing the severity of the possible eye infection. Use of analgesics that are anti-inflammatory (e.g. aspirin) would also invalidate the model since we are studying a model for inflammation of epithelial cells by bacterial invasion.

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 _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 10-F-0002

2. Number 6 of animals used in this study.

3. Species (common name) Rabbit of animals used in the study.

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

Distress due to Busulfan/Ethyl palmitate, the cytotoxic regimen, or due to antibodies used to induce thrombocytopenia in rabbits, may weaken the animal and cause potential symptoms, such as: significant bleeding due to thrombocytopenia (hematoma); nonspecific drug-related adverse events—persistent anorexia, significant injection site reactions, significant decreased ambulation or listlessness; restlessness, repetitive locomotion, and abnormal vocalization.

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)

Any rabbits showing any combination of these signs will be euthanized with euthanasia solution. All other procedure will occur under general anesthesia in these non-survival experiments, so no pain is anticipated. The potential painful procedures, i.e. the cannulation and laparotomy procedures, described in this protocol are essential for creating the conditions necessary to study the stability and efficacy of Multi-function Blood Substitution in vivo. However, every effort will be made to ensure maximum comfort of the animals under anesthesia. There will be a conscious effort by the P.I. and his staff to provide additional consideration for comfort and well being of the animals as is consistent with the scientific integrity of the study. The attending veterinarian was consulted regarding appropriate and humane use of anesthesia to alleviate the pain associated with the surgical procedures in this protocol. Animals that appear distressed or moribund will be euthanized according to section V.D.7 of this protocol.

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 _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 10-F-0002

2. Number 8 of animals used in this study.

3. Species (common name) Swine of animals used in the study.

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

Piglet model for both emetic and lethal response to Staph endotoxins (SE). Piglets are dosed orally with SE. A determination is made of the value of various potential drugs for prophylaxis against emesis (vomiting) and lethal shock. In addition, an evaluation of how late the drugs can be administered after SE-challenge and still retain desired efficacy of response is determined.

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)

The lethal shock that is induced by the lethal SE-challenge with the LD50 test in the positive control animals will necessarily cause pain to these animals. Positive controls are required to validate results. Analgesics would impact the physiological parameters, exacerbating the lethal shock or emesis induced by the SE and compromising analysis of collected data. If the experimental drugs proved their utility, the animals should experience relief, but should they not experience relief then that indicates failure of the drug and is necessary for that reason. In all circumstances, the animals will be under constant veterinary care and will not be subject to any unnecessary pain.

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 _____ CFR _____

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

10-F-0003 440

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

12-05-2001 RCVD

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

ARMED FORCES INSTITUTE OF PATHOLOGY
6825 16TH ST. NW
BLDG 54 RM 5016
WASHINGTON, DC 20306
(202) 782-2100

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	72	4	368		372
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice		3458			3458
Rats	29	16	75		91

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/28/01

NOV 2 6 2003

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 21!

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 14-F-0009

CUSTOMER NUMBER: 463

FORM APPROVED
OMB NO. 0579-0036

U.S.D.A./Human Nutrition Res. Ctr. At Tufts U
711 Washington Street
Boston, MA 02111

Telephone: (617) -556-3200

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

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessarv 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 ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters		37	492		529
8. Rabbits			2		2
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice	3,363	3,199	1,479	279	4,957
Rats	662	183	398		581
Ferrets		70	121		191

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 (Type or Print)	DATE SIGNED
		11-10-0

APHIS FORM 7023 (AUG 91)

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

Jean Mayer
United States Department of Agriculture
Human Nutrition Research Center on Aging
At Tufts University

(b)(4)

Nutritional Immunology Laboratory

October 15, 2001

To:

Animal Care and Use Committee, HNRCA

From:

Re: Category E animals in Amendment to Protocol (b)(4)

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 CO_2 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.

711 Washington Street
Boston, Massachusetts 02111
FAX: (617) 556-3344

To: Animal Care and Use Committee

From: **PI of** (b)(4) **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 D$_3$) Against NNK-induced Lung Carcinogenesis in AJ Mice

Protocol (b)(4) 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 A/J 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 legions 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 protoco[(b)(4)], "Roles of TNF and interleukin-1 in stress-induced cachexia: Effects of age in transgenic mice"

Our protocol[(b)(4)] 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, ie, the understanding and alleviation of physiological or pathological processes leading to sarcopenia, wasting and cachexia.

In[(b)(4)] 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.

[redacted] regarding the report, please do not hesitate to contact me.

711 Washington Street
Boston, Massachusetts 02111
FAX: (617) 556-3344

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 14-F-0010 CUSTOMER NO. 645

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL MARINE FISHERIES SERVICE AQUARIUM
166 WATER STREET
WOODS HOLE, MA 02543
(999) 999-9999

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)*

See Attached Listing
AQUARIUM SEAL POOL

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, expenments, 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					
HARBOR	2	2	0	0	2
SEALS	TEA	CHING			
		ONLY			

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		9/19/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	14-F-0010
Customer Number:	645
Facility:	NATIONAL MARINE FISHERIES SERVICE AQUARIUM 166 WATER STREET WOODS HOLE, MA 02543 (999) 999-9999

NATIONAL MARINE FISHERIES SERVICE AQUARIUM
166 WATER STREET
WOODS HOLE, MA 02543

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 14-F-0010 **CUSTOMER NO.** 645

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL MARINE FISHERIES SERVICE AQUARIUM
166 WATER STREET
WOODS HOLE, MA 02543

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)*

NATIONAL MARINE FISHERIES SERVICE AQUARIUM
WOODS HOLE, MA 02543

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					
HARBOR SEALS	2	2			2

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/26/2001

NOV 1 2 2004

This report is required bylaw (7 USC 2143). Failure to report according to the regulations can result in an order 10 cease and desist and to be subject to penalties as provided for in Section 2150.

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 21-F-0001

CUSTOMER NUMBER: 447

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

USDA, ARS, NAA
Plum Island Animal Disease Ctr
P.O. Box 848
Greenport, NY 11944

Telephone: (516) -323-2500

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

FACILITY LOCATIONS (Sites) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiment, research, or surgery but not ye used for such Purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o' pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for when the use of appropriate anesthetic, analgesic, or tranquilizer drugs would have adversely affected the procedures, research 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 NUMBER OF ANIMALS (COLUMNS C+D+E)
4. Dogs					
5. Cats					
6. Guinea Pigs		4			4
7. Hamsters					
8. Rabbits		7			7
9. Non-human Primates					
10. Sheep		6	46		52
11. Pigs		30	127	106	263
12. Other Farm Animals					
Cattle		4	73	12	89
13. Other Animals					
Horses			10		10
ELK			8		8

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
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 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10-18-04

APHIS FORM 7023
(AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

This report is required bylaw (7 USC 2143). Failure to report according to the regulations can result in an order 10 cease and desist and to be subject to penalties as provided for in Section 2150.

See attached form for additional information.

Interagency Report Control No.:

NOV 1 2 2004

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 21-F-0001

CUSTOMER NUMBER: 447

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

USDA, ARS, NAA
Plum Island Animal Disease Ctr
P.O. Box 848
Greenport, NY 11944

Telephone: (516) -323-2500

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

FACILITY LOCATIONS (Sites) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiment, research, or surgery but not ye used for such Purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o' Pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for when the use of appropriate anesthetic, analgesic, or tranquilizer drugs would have adversely affected the procedures, research 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 NUMBER OF ANIMALS (COLUMNS C+D+E)
Chicken		40		335	375
Mice		10			10

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 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 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
		10-18-04

APHIS FORM 7023A
(AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

Plum Island Animal Disease Center, New York
Annual USDA Report Form
October 15, 2004

An explanation of the procedures producing pain or distress in animals listed in column E and the reasons such drugs were not used:

Animals listed in column E of this annual report of Plum Island Animal Disease Center (PIADC) were infected experimentally with viruses and other agents that cause natural diseases in agricultural animals.

Analgesics were not given to these infected animals when their administration would have masked the clinical signs needed to diagnose their diseases, or demonstrate their signs to students of PIADC's national and international courses.

Animals demonstrating sings of pain were euthanatized as soon as possible in order to minimize pain.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 31-F-0002 CUSTOMER NO. 442

FORM APPROVED OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA include Zip Code)*

OPERATIONAL TOXICOLOGY BRANCH
2760 Q ST, AREA B, AFRL/HEST
WRIGHT-PATTERSON AFB, OH 45433
(999) 999-9999

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)*

See Attached Listing

BUILDING 838 AREA B WPAFB

BUILDING 433 AREA B WPAFB

BUILDING 79 AREA B WPAFB

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			17		17
9. Non-Human Primates					
10. Sheep					
11. Pigs			17		17
12. Other Farm Animals					
13. Other Animals					
FERRETS			8		8

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		15 Jan 07

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 42-F-0007
CUSTOMER NUMBER: 1588

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

03/30/05
mc

Nat'L Ani Dis Center
P.O. Box 70
2300 Dayton Ave
Ames, IA 50010

Telephone: (515) -663-7200

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this repor	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters		15	4	3	22
8. Rabbits			6		6
9. Non-human Primates					
10. Sheep		125	80		205
11. Pigs		391	20	194	605
12. Other Farm Animals					
Cattle		231	20	18	269
13. Other Animals					
Bison		105			105
Elk		26			26
WT Deer		71			71

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 app 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 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 & 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 10 2004

This report is required by law (7 USC 2143). Failure to [illegible] according to the regulations can result in an order to cease and desist and to be subject [illegible] penalties as provided for in Section 2150. See [illegible] side for additional information. Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

COPY

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO.
42-F-0007 Cust. #1588

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Nat'l Ani Dis Center
P.O. Box 70
2300 Dayton Avenue
Ames, IA 50010

Telephone: 515-663-7200

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12. &/OR 13. Other *(List by species)*	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)
12. Goats		14			14
Horse		2			2
13. Reindeer		17			17
Raccoons		2	43		45

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

DEC 10 2004

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

Registration #42-F-007
National Animal Disease Center

Explanation of protocols for Category III animals listed on the APHIS Report Form 7023 submitted by NADC - October 1, 2003 - September 30, 2004

Studies include 271 animals: Cattle, Swine, Hamsters

Cattle:

1. This a study of characterization and modulation of Bovine Diarrhea Virus virulence. The pathological effects of the infection are to be evaluated. The pathological effects expected may include malaise, listlessness, anorexia, or diarrhea. Symptoms are the result of vascular leakage caused by the virus infection. The objective of the study is to determine if differences in genomic sequences or protein processing correlate with differences in pathology.

2. Anti-diarrheal or anti-spasmodic drugs, and drugs that would increase the clotting ability of the blood would interfere in normal manifestation of the disease and may alter the pathology. To minimize the animal discomfort, the platelet counts are monitored, and all animals with platelet counts below 10,000 will be euthanatized. The animals in Cat. I are the animals that did not exhibit any pain or distress (controls that were not challanged) and the animals that were euthanatized as the result of low platelet count. The disease had not progressed beyond exhibition of mild symptoms of the disease. The Cat. III animals are those that went off feed, became weak and/or developed diarrhea before the platelet count was below 10,000. On the basis of these symptoms these animals were also euthanized.
   Cat. I 23: Cat. III - 12: Total - 35

1. The objective is to study the immune function of both early and late disease infection in the cow, the target species. An associated objective is to test and evaluate diagnostic tools for detection of bovine paratuberculosis.

2. Paratuberculosis is a chronic disease, and study of the disease requires the observation and sample collection from the animals over several years. Symptoms of the disease; diarrhea, weight loss, and inappetence for up to 7 years, may occur and must be manifested for evaluation of the disease. Animals that exhibit severe weight loss, body condition (some below 2.0 - Penn State University), or are recumbent over 24 hours will be euthanized.
   Cat. I -41: Cat. III - 2: Total - 43

1. The objective of the study is to determine if, when, or how 0157:H7 E. coli and other Shiga toxin-producing E. coli colonize and cause lesions in the gut of weaned calves. The parameters stated include shedding of organisms and histologic lesions. The study requires the disease be allowed to develop and symptoms be manifest.

2. The use of interventions (treatments) anti-microbial that might prevent the pain or distress of diarrhea associated with 0157

NADC #42-F-007

(Cattle continued)

colonization would interfere with colonization and interpretation of the results of the study.
Cat. I -2: Cat. III - 2: Total - 4

1. The objective is to determine the efficacy of intimin vaccines in cattle. Fecal samples will be collected before and after inoculation for bacterial counts and antibodies, and as need for diagnostic microbiology.

2. The use of interventions (treatments) anti-microbial that might prevent the pain or distress of diarrhea associated with 0157 colonization would interfere with colonization and interpretation of the results of the study.
Cat. I -14: Cat. III - 2: Total - 16

Swine:

1. The objective of this research is to identify S.Typhimurium genes involved in survival during exposure to the swine stomach. The harsh environment of the stomach is the host's first line of defense following ingestion of a Salmonella-contaminated substance. Our goal is to understand how Salmonella survives exposure to the porcine stomach since swine are an important reservoir of the food-borne pathogen. An understanding of these survival mechanism may assist in the development of more effective prevention strategies.

2. Validity of the experimental results require that the infectious disease induced by S. Typhimurium be allowed to manifest itself without the use of therapeutic drugs. Otherwise, the altered state of the host due to the use of antimicrobials will change the clinical response, potentially modifying the observed pathogenicity of the Salmonella mutants.
Cat. I -0: Cat. III -12: Total - 12

1. The objective of the study is to determine which pathogens act as primary agents predisposing to secondary infection in respiratory disease in swine.

2. Only mild respiratory disease signs are expected. In this study of 40 pigs, 30 develop mild signs, they needed to be allowed to develop to the point of causing some distress in the pig; anorexia, pyrexia, dyspnea, coughing, and nasal discharge. Administration of therapeutics to reduce the symptoms would interfere in manifestation of the disease in pigs, therefore, could not be given. If signs become severe and pigs unable to rise, they were euthanized. No pigs required euthanasia prior to the end of the two week study.
Cat. I -10: Cat. III -30: Total - 40

1. Objective of study is to evaluate the pathogenesis of SIV field isolates and the efficacy of SIV vaccines. SIV causes major economic losses to swine producers. We do not have any information

NADC #42-F-007

(Swine Continued)

of the pathogenesis of newly emerged SIV's and on the efficacy of vaccines against these viruses.

2. Severe clinical signs are not expected following inoculation of pigs with SIV. Mild clinical signs consisting of pyrexia, anorexia, listlessness, sneezing, and coughing could develop. The onset of clinical signs is necessary to judge the pathogenic effects of the challenge virus and also to evaluate the efficacy of the respective vaccines.
Cat. I -22: Cat. III -144: Total - 75

1. Objective of study to investigate the pathogenesis of a putative new filterable agent that is thought to be the etiologic agent for an epidemic of vesicular disease reported in the field. Significance: tissue samples from this epidemic were tested by the Foreign Animal Disease Laboratory at Plum Island and no known viral vesicular disease agents were identified in the tissues. So, this epidemic of vesicular disease has an unknown etiology, and it is important to determine what the etiology was.

2 Following challenge, mild clinical signs consisting of anorexia and listlessness may develop along with possible vesicular lesions on the snout, oral cavity, and coronary band. The onset of clinical signs is necessary to judge the pathogenic effects of the challenge and to study the pathogenesis of the disease. Drugs that might alleviate the clinical signs would obscure the pathogenic effects of the challenge and thus the pathogenesis of the disease.
Cat. I - 16: Cat. III - 8: Total - 24

Hamsters:

1. The purpose of the study is to evaluate leptospira clones for virulence. Weanling hamsters will be inoculated with live organisms.

2. Observation of clinical signs and how signs progress is necessary to evaluate virulence. Alleviation or relieving of the signs would interfere in the assessment. The pain would be the result of severe hemorrhage, or vascular leakage. The primary signs used to evaluate the disease are jaundice or hemorrhage. To relieve the pain or distress as the result of the infection would reduce the level of jaundice or hemorrhage. To minimize severe or terminal signs, animals are observed every eight hours and any animal exhibiting hemorrhage is euthanized. The Cat. I animals are those that show no signs of pain or distress; Cat. II are those that are detected with jaundice early and are given pentobarbital; and Cat. III are those that die acutely before jaundice or hemorrhage.
Cat. I - 15: Cat. II -4: Cat. III - 3: Total - 22

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 42-F-0008
CUSTOMER NUMBER: 1726

FORM APPROVED
OMB NO. 0579-0036

CVB-VS-APHIS-USDA
1800 Dayton Rd
Ames, IA 50010

Telephone: (515) 663-8331

COPY

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this repon	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		10			10
5. Cats					
6. Guinea Pigs		245	155	40	440
7. Hamsters		2202		707	2909
8. Rabbits		31	161	9	201
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 app 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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		29-Nov-04

APHIS FORM 7023 (AUG 91) (Replaces VS (OCT 88), which is obsolete.)

NOV 30 2004

November 29, 2004

Annual report of the Center for Veterinary Biologics (CVB) for the period of October 1, 2003, through September 30, 2004.

1. All facilities are located at the 1800 Dayton Road location.

2. Statement of reasons for not using drugs in experiments involving pain and distress:

The CVB-L's main function is the testing of veterinary biologicals for safety, efficacy, and purity. Drugs to alleviate pain and distress produced by the infectious disease agents are contraindicated as they suppress the immune system causing the disease to be more severe and run a longer course. Most cases are also not allowed according to the requirements found in the 9 CFR, Chapter 113. Making sick animals comfortable and disturbing them as little as possible provides better treatment to these animals and quicker recovery than occurs by administering pain relievers. Euthanasia or curative treatments are employed as soon as allowed by the Animal Care and Use Committee approved animal use procedure.

3. Exceptions to adherence to the standards and regulations under the Act: None

4. Protocols involving unrelieved pain or distress were as follows:

See following attachments for Facility 42-F-008

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by a lay persons as well as scientists.

1. Registration Number: 42-F-0008

2. Number 138 (31 in Cat. E) of animals in this study.

3. Species (common name) Guinea Pigs of animals used in the study.

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

Clostridium chauvoei and C. haemolyticum challenge tests- animals became ill from challenge with these organisms as required by 9 CFR 113.

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)

Mandated by 9 CFR 113

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):

APHIS, 9 CFR 113.106 and 113.107

FY 2004

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs and the like, are not required as part of an explanation . A Column E explanation must be written so as to be understood by a lay persons as well as scientists.

1. Registration Number: 42-F-0008

2. Number 74 (9 in Cat E) of animals in this study.

3. Species (common name) Guinea Pigs of animals used in the study.

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

Potency testing of tetanus toxoids and antitoxins - animal getting insufficient protection from the tetanus antitoxin become sick from tetanus toxin challenge..

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)

Mandated by 9 CFR 113

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):

   APHIS, 9CFR 113.114 and 113.451

FY2004

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs and the like, are not required as part of an explanation . A Column E explanation must be written so as to be understood by a lay persons as well as scientists.

1. Registration Number: 42-F-0008

2. Number 2909 (707 in Cat. E) of animals in this study.

3. Species (common name) Hamsters of animals used in the study.

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

Evaluation of Leptospira Bacterins and maintenance of challenge cultures cause animals to experience Leptospirosis -

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)

Mandated by 9 CFR 113

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):

APHIS, 9CFR 113.101, 113.102, 113.103, and 113.104 which are all Leptospirosis tests.

FY 2004

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by a lay persons as well as scientists.

1. Registration Number: 42-F-0008

2. Number 29 (9 in Cat. E) of animals in this study.

3. Species (common name) Rabbit of animals used in the study.

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

Clostridium haemolyticum challenge tests- animals became ill from challenge with these organisms as required by 9 CFR 113 for guinea pigs. Rabbits were substituted for guinea pigs based on an APHIS approved Outline of Production.

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)

Mandated by 9 CFR 113 for guinea pigs and APHIS approved the rabbit substitute.

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):

APHIS, 9 CFR 113.107

FY 2004

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

12-03-2001 RCVD

1. REGISTRATION NO. 51-F-0001 CUSTOMER NO. 432

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIFORMED SERVICES
UNIV. OF THE HEALTH SCIENCES
4301 JONES BRIDGE RD.
BETHESDA, MD 20814
(301) 295-1909

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)*

See Attached Listing

Center of Laboratory Animal Medicine

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	23	0	23
8. Rabbits	0	0	10	0	10
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	37	0	37
11. Pigs	0	53	324	0	377
12. Other Farm Animals					0
Goats	0	0	113	0	113
13. Other Animals					0
Ferret	0	37	99	0	136
Sand Rat	103	28	52	0	80
Cotton Rat	0	0	30	0	30

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-30-01

APHIS FORM 7023 (AUG 91) (Replaces 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 21!

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-F-0003
CUSTOMER NUMBER: 443

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Armed Forces Radiobiology Research Inst.
Afrri/Vsd
8901 Wisconsin Avenue
Bldg 42
Bethesda, MD 20889

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

FACILITY LOCATIONS (Sites) - See Atached Listing

All animals located on-site

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 ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	23		20		20
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates			86		86
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice		3004	1579	6112	10,695
Rats		75	492		492

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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.	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED

APHIS FORM 7023
(AUG 91)

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

Registration No. 51-F-003

Armed Forces Radiobiological Research Institute
8901 Wisconsin Ave. Bldg. 42
Bethesda, MD 20889-5603

Attachment to APHIS FORM 7023

Pain Category "E" Justification

Protocol 1 - 440 mice

The research questions that we are attempting to address involve complex interactions between different tissues that would be affected by the administration of drugs to alleviate pain. The pain associated with the radiation experiments derives from the fact that the animals succumb to infections because of compromised immune systems. Because of the physiological complexity of radiation injury, and our lack of having a full understanding of its induction and progression, there is just no alternatives to evaluate the effectiveness of the proposed drug (tocopherol succinate) other than to conduct survival studies in mice without the interference of the analgesia.

Protocol 2 – 90 mice

Since the purpose of our study was to determine the effects of radiation and radioprotectants on the functions of the immune system, we did not use analgesics and anesthetics. Alterations of the immune system by analgesics and anesthetics have been documented in literature and have been referred to in the IACUC protocol.

Protocol 3 – mice 80

There are no alternative procedures for irradiation because it is a unique stimulus that cannot be otherwise duplicated. Radiation itself does not cause pain or distress. In fact, radiation can alleviate the pain associated with cancer (Bateman, 1994; Ciezki and Macklis, 1995; Page, 1995; Sonoo et al., 1995; Thrall, 1995). Nevertheless, the sequelae of nausea, vomiting, and diarrhea cause pain and distress in humans in the early post-irradiation period, when lethal doses are used. However, mice are not susceptible to vomiting. Although radiation does not induce pain, animals in these experiments might experience pain and distress prior to death because of sequelae. To avoid possibly affecting survival/death outcomes, and ultimately $LD_{50/30}$ and $LD_{95/30}$ calculations, analgesics/sedatives will not be administered after challenge so as not to interfere with the clinical course of the disease. The attending veterinarian was

consulted with respect to the procedures described above, when they were used on previous protocols.

Bacteria cause infections that cause discomfort either locally or systemically. Many pathogenic bacteria have unusual or even unique virulent characteristics, but they also have common attributes, including binary multiplication and penetration of tissues, and cause common responses and disease processes in animals, which cannot be mimicked readily by substitutes. Although, by necessity, there are animals included in the unalleviated pain-and-distress category in this protocol, there will be a conscious effort by the P.I. and animal care staff to provide as much additional consideration for the comfort and well-being of the animals as is consistent with the scientific integrity of the study. These studies are designed to assess the susceptibility and immune response to the combined effects of ionizing radiation and bacterial infection. There are no alternatives to the use of animals in these studies. Similarly, there are no alternatives to bacterial challenge or natural, radiation-induced infection, because protective immunity cannot be predicted from seroconversion alone at this time when it occurs. Moribund animals will be euthanized as indicated below to alleviate further pain and distress.

Although we expect that test therapeutic agents will provide some relief to some of the mice, an alternative for these procedures would be to determine whether an analgesic could be used to relieve pain and discomfort. Although the opioid analgesics, butorphanol and bupenorphine, might be used to alleviate local pain associated with a local infection without altering the local inflammatory response (Swearengen et al. 1993), opioid analgesics are immunomodulatory (Pruett et al. 1992, Pasotti et al. 1993, Carr et al. 1994). Other, non-narcotic analgesics, such as indomethacin, are anti-inflammatory, so they would interfere with the inflammatory responses of the hemopoietic tissues to infections. Analgesics cause adverse effects on undamaged hematopoietic cells (Hollaender, 1960) and interfere with nicotinamide-adenine dinucleotide phosphate (NADPH) oxidase, a key polymorphonuclear leukocyte enzyme that is involved in the ability of these cells to phagocytize and kill bacteria (Moon et al., 1986).

Protocol 4 – 424 mice

The animals in Category E were placed into that category because they were in experiments where mortality occurred due to radiation-induced compromise of the immune system, resulting in opportunistic infection. Pain and distress was judged to occur as a result of the infection, i.e., what humans would experience as flu-like symptoms. Although not all animals in those experiments died from infection, some animals may have suffered the effects of infection and then recovered. Therefore, all animals in those experiments were placed into Category E. These survival experiments were essential for evaluating the efficacy of candidate radioprotective drugs. Anesthetics and analgesics could not

be used during the course of these experiments because they would have affected the immune system, making the results uninterpretable.

Protocol 5 - 1133 mice

The research questions that we are addressing involve complex interactions between many tissues that would be affected by the administration of drugs to alleviate pain. The pain and distress experienced by these animals would probably be similar to what humans experience during severe cold and flu infections. Radiation itself has been demonstrated to reduce pain in laboratory mice (Teskey and Kavaliers 1984) and has been reported to alleviate cancer related bone pain in humans (Ciezki and Macklis 1995; Sonoo et al. 1995). The isoflavones used in these experiments have been shown to enhance the immune system and reduce pain (Shir et al. 2002) and inflammation (Verdrengh et al., 2003), and will likely reduce radiation-induced discomfort. Because of the complexity of physiological responses that occurs after radiation exposure, and our poor understanding of its induction and progression, there is no other way, at present, to evaluate the effectiveness of radiation protectants to enhance survival of humans than to do these experiments in animals. One of the aims of the present study is to acquire an understanding of cellular and molecular correlates of radioprotection in order to develop techniques to evaluate these compounds with less reliance on animal studies.

Protocol 6 –1546 mice

Specific analgesics will not be used in any of the experiments because of the potential of confounding the clinical assessment of the animals. Although the opioid analgesics, butorphanol and bupenorphine, might be used to alleviate local pain associated with a local infection without altering the local inflammatory response (Swearengen et al. 1993), opioid analgesics have been shown to have immunomodulatory properties (Pruett et al. 1992, Pasotti et al. 1993, Carr et al. 1994). Other, non-narcotic analgesics, such as indomethacin, are anti-inflammatory, so they would interfere with the inflammatory responses of the hemopoietic tissues to infections. Hemopoietic tissues are already depleted in irradiated animals. Further, sedatives cause adverse effects on undamaged hematopoietic cells (Hollaender, 1960) and interfere with nicotinamide-adenine dinucleotide phosphate (NADPH) oxidase, a key polymorphonuclear leukocyte enzyme that is involved in the ability of these cells to phagocytize and kill bacteria (Moon et al., 1986).

Protocol 7 – 19 mice

The radiation procedure will be presumed to cause pain and that pain will not be alleviated. Irradiation itself does not directly cause pain or distress; only the sequelae of nausea and vomiting do. Mice, like other rodents, do not vomit but do show conditioned taste aversion (CTA) and delayed gastric emptying, even after such low doses of radiation. Although this species has not been evaluated for radiation-induced CTA, it likely occurs. Because the action of irradiation must be done *in vivo*, the only viable alternative for these procedures would be to determine whether an analgesic could be used to relieve the pain and distress (i.e., CTA) associated with radiation. It is unclear whether pain and distress is associated with altered gastric emptying or the GI motility changes that we plan to study after sublethal irradiation. While the opioid analgesics butorphanol and bupenorphine have been used by others to alleviate pain, such compounds are known to cause immunomodulation, which in turn would confound the radiation effects. Other, non-narcotic analgesics such as indomethacin are anti-inflammatory and as such would interfere with the inflammatory responses of the normal tissue to irradiation. Such compounds also cause adverse effects on undamaged hematopoietic cells and interfere with nicotinamide-adenine dinucleotide phosphate (NADPH) oxidase, a key polymorphonuclear leukocyte enzyme involved in the ability of these cells to phagocytize and kill bacteria. Because we are affecting the GI immune system with irradiation in this study, we cannot use pain-relieving drugs that would modulate those responses.

Protocol 8 – 1812 mice

Since the purpose of our study was to determine the effects of radiation and radioprotectants on the functions of the immune system, we did not use analgesics and anesthetics. Alterations of the immune system by analgesics and anesthetics have been documented in literature and have been referred to in the IACUC protocol.

Protocol 9 – 568 mice

The use sedatives and analgesics will be used with a degree of caution and on an individual animal-in-need basis. Reasons for our proposed limited use of sedatives and analgesics only in cases of severe pain/discomfort are as follows: (1) in mice, clinical signs of minimal or even moderate pain/discomfort have the potential to interfere with the identification of clinical signs and alter the hematological and survival responses of the treated animals, and (b) the use and analgesics and anesthetics on an individual basis might interfere with basic functional elements of the irradiated animal's innate and acquired immune system. In this regard for example, there is a wealth of information that clearly documents the effect of sedatives and opiates on neutrophil production and function.

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 21

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-F-0003
CUSTOMER NUMBER: 443

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Armed Forces Radiobiology Research Inst. NOV 2 9 2004
Afrri/Vsd
8901 Wisconsin Avenue
Bldg 42
Bethesda, MD 20889

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

All animals located on-site

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates	24		59		59
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice		3400	622	5,927	9,949
Rats			83		83

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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)

SIGNATUI	TITUTIONAL OFFICI	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED

APHIS FOR (Repl ORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

Registration No. 51-F-003

Armed Forces Radiobiological Research Institute
8901 Wisconsin Ave. Bldg. 42
Bethesda, MD 20889-5603

Attachment to APHIS FORM 7023

Pain Category "E" Justification

Protocol 1 - 914 mice

The research questions that we are attempting to address involve complex interactions between different tissues that would be affected by the administration of drugs to alleviate pain. The pain associated with the radiation experiments derives from the fact that the animals succumb to infections because of compromised immune systems. Because of the physiological complexity of radiation injury, and our lack of having a full understanding of its induction and progression, there is just no alternatives to evaluate the effectiveness of the proposed drug (tocopherol succinate) other than to conduct survival studies in mice without the interference of the analgesia.

Protocol 2 - 412 mice

Since the purpose of our study was to determine the effects of radiation and radioprotectants on the functions of the immune system, we did not use analgesics and anesthetics. Alterations of the immune system by analgesics and anesthetics have been documented in literature and have been referred to in the IACUC protocol.

Protocol 3 - 417 mice

There are no alternative procedures for irradiation because it is a unique stimulus that cannot be otherwise duplicated. Radiation itself does not cause pain or distress. In fact, radiation can alleviate the pain associated with cancer (Bateman, 1994; Ciezki and Macklis, 1995; Page, 1995; Sonoo et al., 1995; Thrall, 1995). Nevertheless, the sequelae of nausea, vomiting, and diarrhea cause pain and distress in humans in the early post-irradiation period, when lethal doses are used. However, mice are not susceptible to vomiting. Although radiation does not induce pain, animals in these experiments might experience pain and distress prior to death because of sequelae. To avoid possibly affecting survival/death outcomes, and ultimately $LD_{50/30}$ and $LD_{95/30}$ calculations, analgesics/sedatives will not be administered after challenge so as not to interfere with the clinical course of the disease. The attending veterinarian was

consulted with respect to the procedures described above, when they were used on previous protocols.

Bacteria cause infections that cause discomfort either locally or systemically. Many pathogenic bacteria have unusual or even unique virulent characteristics, but they also have common attributes, including binary multiplication and penetration of tissues, and cause common responses and disease processes in animals, which cannot be mimicked readily by substitutes. Although, by necessity, there are animals included in the unalleviated pain-and-distress category in this protocol, there will be a conscious effort by the P.I. and animal care staff to provide as much additional consideration for the comfort and well-being of the animals as is consistent with the scientific integrity of the study. These studies are designed to assess the susceptibility and immune response to the combined effects of ionizing radiation and bacterial infection. There are no alternatives to the use of animals in these studies. Similarly, there are no alternatives to bacterial challenge or natural, radiation-induced infection, because protective immunity cannot be predicted from seroconversion alone at this time when it occurs. Moribund animals will be euthanized as indicated below to alleviate further pain and distress.

Although we expect that test therapeutic agents will provide some relief to some of the mice, an alternative for these procedures would be to determine whether an analgesic could be used to relieve pain and discomfort. Although the opioid analgesics, butorphanol and bupenorphine, might be used to alleviate local pain associated with a local infection without altering the local inflammatory response (Swearengen et al. 1993), opioid analgesics are immunomodulatory (Pruett et al. 1992, Pasotti et al. 1993, Carr et al. 1994). Other, non-narcotic analgesics, such as indomethacin, are anti-inflammatory, so they would interfere with the inflammatory responses of the hemopoietic tissues to infections. Analgesics cause adverse effects on undamaged hematopoietic cells (Hollaender, 1960) and interfere with nicotinamide-adenine dinucleotide phosphate (NADPH) oxidase, a key polymorphonuclear leukocyte enzyme that is involved in the ability of these cells to phagocytize and kill bacteria (Moon et al., 1986).

Protocol 4 - 664 mice

The animals in Category E were placed into that category because they were in experiments where mortality occurred due to radiation-induced compromise of the immune system, resulting in opportunistic infection. Pain and distress was judged to occur as a result of the infection, i.e., what humans would experience as flu-like symptoms. Although not all animals in those experiments died from infection, some animals may have suffered the effects of infection and then recovered. Therefore, all animals in those experiments were placed into Category E. These survival experiments were essential for evaluating the efficacy of candidate radioprotective drugs. Anesthetics and analgesics could not

be used during the course of these experiments because they would have affected the immune system, making the results uninterpretable.

Protocol 5 - 607 mice

The research questions that we are addressing involve complex interactions between many tissues that would be affected by the administration of drugs to alleviate pain. The pain and distress experienced by these animals would probably be similar to what humans experience during severe cold and flu infections. Radiation itself has been demonstrated to reduce pain in laboratory mice (Teskey and Kavaliers 1984) and has been reported to alleviate cancer related bone pain in humans (Ciezki and Macklis 1995; Sonoo et al. 1995). The isoflavones used in these experiments have been shown to enhance the immune system and reduce pain (Shir et al. 2002) and inflammation (Verdrengh et al., 2003), and will likely reduce radiation-induced discomfort. Because of the complexity of physiological responses that occurs after radiation exposure, and our poor understanding of its induction and progression, there is no other way, at present, to evaluate the effectiveness of radiation protectants to enhance survival of humans than to do these experiments in animals. One of the aims of the present study is to acquire an understanding of cellular and molecular correlates of radioprotection in order to develop techniques to evaluate these compounds with less reliance on animal studies.

Protocol 6 - 540 mice

Specific analgesics will not be used in any of the experiments because of the potential of confounding the clinical assessment of the animals. Although the opioid analgesics, butorphanol and bupenorphine, might be used to alleviate local pain associated with a local infection without altering the local inflammatory response (Swearengen et al. 1993), opioid analgesics have been shown to have immunomodulatory properties (Pruett et al. 1992, Pasotti et al. 1993, Carr et al. 1994). Other, non-narcotic analgesics, such as indomethacin, are anti-inflammatory, so they would interfere with the inflammatory responses of the hemopoietic tissues to infections. Hemopoietic tissues are already depleted in irradiated animals. Further, sedatives cause adverse effects on undamaged hematopoietic cells (Hollaender, 1960) and interfere with nicotinamide-adenine dinucleotide phosphate (NADPH) oxidase, a key polymorphonuclear leukocyte enzyme that is involved in the ability of these cells to phagocytize and kill bacteria (Moon et al., 1986).

Protocol 7 - 23 mice

The radiation procedure will be presumed to cause pain and that pain will not be alleviated. Irradiation itself does not directly cause pain or distress; only the sequelae of nausea and vomiting do. Mice, like other rodents, do not vomit but do show conditioned taste aversion (CTA) and delayed gastric emptying, even after such low doses of radiation. Although this species has not been evaluated for radiation-induced CTA, it likely occurs. Because the action of irradiation must be done in vivo, the only viable alternative for these procedures would be to determine whether an analgesic could be used to relieve the pain and distress (i.e., CTA) associated with radiation. It is unclear whether pain and distress is associated with altered gastric emptying or the GI motility changes that we plan to study after sublethal irradiation. While the opioid analgesics butorphanol and bupenorphine have been used by others to alleviate pain, such compounds are known to cause immunomodulation, which in turn would confound the radiation effects. Other, non-narcotic analgesics such as indomethacin are anti-inflammatory and as such would interfere with the inflammatory responses of the normal tissue to irradiation. Such compounds also cause adverse effects on undamaged hematopoietic cells and interfere with nicotinamide-adenine dinucleotide phosphate (NADPH) oxidase, a key polymorphonuclear leukocyte enzyme involved in the ability of these cells to phagocytize and kill bacteria. Because we are affecting the GI immune system with irradiation in this study, we cannot use pain-relieving drugs that would modulate those responses.

Protocol 8 - 1310 mice

Since the purpose of our study was to determine the effects of radiation and radioprotectants on the functions of the immune system, we did not use analgesics and anesthetics. Alterations of the immune system by analgesics and anesthetics have been documented in literature and have been referred to in the IACUC protocol.

Protocol 9 - 984 mice

The use sedatives and analgesics will be used with a degree of caution and on an individual animal-in-need basis. Reasons for our proposed limited use of sedatives and analgesics only in cases of severe pain/discomfort are as follows: (1) in mice, clinical signs of minimal or even moderate pain/discomfort have the potential to interfere with the identification of clinical signs and alter the hematological and survival responses of the treated animals, and (b) the use and analgesics and anesthetics on an individual basis might interfere with basic functional elements of the irradiated animal's innate and acquired immune system. In this regard for example, there is a wealth of information that clearly documents the effect of sedatives and opiates on neutrophil production and function.

Protocol 10 - 56 mice

As described above in the sections on "Non-animal Alternatives" considered and "Anesthesia/Analgesia/Tranquilization", the research questions that we are attempting to address involve complex interactions between different tissues that would be affected by the administration of drugs to alleviate pain. Although all painful procedures such as injection of the tumor cells and irradiation will be done under anesthesia, animals may experience discomfort and pain as a result of the postirradiation tissue injury and tumor growth. Pain arising out of the postirradiation sequelae and tumor growth cannot be alleviated since it may interfere with the objective of the study. The hypothesis of the protocol, viz., preferential protection of normal tissue by TT during irradiation of prostate tumor is based on the assumption of the differential distribution of TT in favor of the normal tissue. Administration of analgesics may affect the partitioning of TT between normal and tumor tissue and the results derived may not be conclusive. Influence of drugs and other factors on permeation of other drugs has been reported earlier (11,12). Since postirradiation sequelae and tumor growth may cause pain and discomfort, which will not be alleviated with analgesics, all mice other than unirradiated controls will be under the unalleviated pain category (E).

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

11-23-2001 RCVD

1. REGISTRATION NO.
443 51-F-0003

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Armed Forces Radiobiology Research Institute
8901 Wisconsin Avenue, Building 42
Bethesda, MD 20889-5603

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)*

All animals housed/used within the AFRRI Complex (above address)

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	32	0	22	0	22
5. Cats					
6. Guinea Pigs		0	178	0	178
7. Hamsters					
8. Rabbits		0	30	0	30
9. Non-human Primates		0	189	0	189
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets		0	10	0	10

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
		16 Nov 01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

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 21! NOV 30 2004 See attached form for additional information. Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-F-0006
CUSTOMER NUMBER: 437

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

U.S. Army Medical Research
Institute Of Chemical Defense
Attn: Mcmr-Uv-Za
3100 Ricketts Point Road
Aberdeen Prov Grnd, MD 21010

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBEF OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	782	335	2,158	3,275
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	5	2	36	15	53
10. Sheep	0	0	0	0	0
11. Pigs	0	3	34	0	37
12. Other Farm Animals					
N/A					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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. TUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		24 NOV 2004

APHIS FORM (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 1

1. A total of 334 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: The administration of anesthetics or analgesics to relieve pain would lead to an erroneous evaluation of the toxicity of agents and efficacy of pretreatment, treatment, and decontamination procedures.

4. No federal regulations mandate this procedure.

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 2

1. A total of 635 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: Anesthetics or analgesics cannot be used in any of the procedures involving agent administration and/or pretreatment and treatment with any of the medical countermeasures. One of the principle effects of agent intoxication is respiration paralysis. This is also a major side effect of anesthetics and analgesics. Conducting these experiments under anesthesia or analgesia could lead to faulty interpretation of the toxicity data and/or the effectiveness of the countermeasures because of the synergistic respiratory depressant effects of these drugs with the agent.

4. No federal regulations mandate this procedure.

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 3

1. A total of 20 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: Should it occur, pain/distress might be relieved to some extent by administration of one of the test drugs that successfully terminates the seizure. Anesthetics and analgesics are known to have profound effects on brain function that can interact with the drugs of interest, the synthesis and release of brain neurotransmitters and/or the toxicity of the nerve agent and thus complicate interpretation of the results.

4. No federal regulations mandate this procedure.

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 4

1. A total of 54 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: Should it occur, pain/distress might be relieved to some extent by administration of one of the test drugs that successfully terminates the seizure. Anesthetics and analgesics are known to have profound effects on brain function that can interact with the drugs of interest, the synthesis and release of brain neurotransmitters and/or the toxicity of the nerve agent and thus complicate interpretation of the results.

4. No federal regulations mandate this procedure.

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 5

1. A total of 9 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: Treatment of these animals with standard nerve agent therapies such as atropine and oxime would prevent the accurate correlation of acetylcholinesterase inhibition and neuronal function that is a goal of this study.

4. No federal regulations mandate this procedure.

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 6

1. A total of 588 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: The administration of anesthetics or analgesics to relieve pain are known to have profound effects on brain, tissue, and organ function that can interact with the synthesis and release of brain neurotransmitters, and/or the toxicity of nerve agent and thus complicate interpretation of the results.

4. No federal regulations mandate this procedure.

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 7

1. A total of 82 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: The administration of anesthetics or analgesics to relieve pain would lead to an erroneous evaluation of the toxicity of agents and efficacy of pretreatment, treatment, and decontamination procedures.

4. No federal regulations mandate this procedure

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 8

1. A total of 402 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: The administration of anesthetics or analgesics to relieve pain are known to have profound effects on brain function, to include electrical seizure activity in the brain that can interact with the drugs and would complicate interpretation of results.

4. No federal regulations mandate this procedure

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 9

1. A total of 19 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: The administration of anesthetics or analgesics to relieve pain are known to have profound effects on toxicity of nerve agents and, thus, can complicate interpretation of results.

4. No federal regulations mandate this procedure

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 10

1. A total of 15 column "E" guinea pigs were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: The administration of anesthetics or analgesics to relieve pain would lead to an erroneous evaluation of the toxicity of agents and efficacy of pretreatment, treatment, and decontamination procedures.

4. No federal regulations mandate this procedure

Column E Explanation Form
USAMRICD – FY 04
Registration Number: 51-F-0006

Protocol 11

1. A total of 15 column "E" nonhuman primates were utilized in this study.

2. Painful procedure: Animals will receive a convulsive dose of an agent which is thought (but not documented) to cause some pain and/or distress due to the intense physical activity caused by the seizure.

3. Justification: Anesthetics and analgesics are known to have profound effects on brain function that can interact with the drugs of interest and/or the toxicity of the nerve agent and thus complicate the interpretation of the results.

4. No federal regulations mandate this procedure.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0008 **CUSTOMER NO.** 438

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL CANCER INSTITUTE
BUILDING ~~429~~ 571
P.O. BOX B
FREDERICK, MD 21702
(301) 846-~~7133~~ 5195

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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		79	94		173
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/6/01

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 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 51-F-0012
CUSTOMER NUMBER: 529

FORM APPROVED
OMB NO. 0579-0036

Agricultural Research Service
Usda-Ars-Anri, Bldg.209, Barc-East
Beltsville, MD 20705

Telephone: (301) -504-8431

DEC 01 2004

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats		655	0	0	655
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		8	1	0	9
9. Non-human Primates					
10. Sheep		51	0	0	51
11. Pigs		261	0	0	261
12. Other Farm Animals		19	0	0	19
13. Other Animals					
mice		7,866	971	429	9,266
rats		130	20	0	150
gerbil		25	0	0	25

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-17-04

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number:_____

2. Number 444 of animals used in this study.

3. Species (common name) mice of animals used in this study.

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

The research focuses on the effect of deficiencies in antioxidant nutrients on immunity to bacterial and viral infections. Some of the bacterial and viral infections may cause morbidity and mortality although all efforts are made to minimize the numbers. Additional experiments looking at the effect of mutated glucans on salmonella virulence requires that mice be monitored until signs of morbidity appear. Mice are then euthanized. However, in some cases the mice succumb rapidly and may become moribund and die in less than a day, thus it is unavoidable that some mice may experience some pain and/or distress. Again, use of analgesics would interfere with the normal course of infection, thus making interpretation of the results more difficult.

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.

Administration of analgesics to mice can affect the inflammatory and immune response of the mice to the infection which would add a confounding variable to the data that would make it impossible to determine what affects are due to the deficiencies and which are due to the analgesics.

UNITED STATED DEPARTMENT OF AGRICULTURE
Agricultural Research Service

DEC 0 1 2003

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 51-F-0012

CUSTOMER NUMBER: 529

FORM APPROVED
OMB NO. 0579-0036

Agricultural Research Service
USDA-ARS-ANRI, Building 209, BARC-East
Beltsville, MD 20705

Telephone: (301) 504-5714

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

FACILITY LOCATIONS (Sites) – See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OD RESEARCH FACILITY (Attach additional sheets if necessary or use this form.

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 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 procedure 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		18			18
5. Cats	14	499			499
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	1	8			8
9. Non-human Primates					
10. Sheep	10	70			70
11. Pigs	84	257			257
12. Other Farm Animals					
Cattle	221	62			62
Goats		3			3
13. Other Animals					
Gerbils		68			68
Rats		54			54
Mice		2338	498		2871

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 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 animal report. In addition to identifying the IACUG 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 HEADQUAARTERS 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
		11-24-03

APHIS F 023
(AU

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

Attachment

Certificate number: 51-F-0012
Customer number: 529

3. Reporting Facility Locations

Buildings: 203, 224, 239, 254, 255, 267, 308C, 337A, 1018, 1019, 1062, 1063, 1064, 1080, 1081, 1082, 1083, 1126, 1140, 1144, 1160, 1182, 1207, 1253, 1254, 1255, 1291, 1292, 1325, 1380, 1381, 1382, 1383, 1384

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-F-0012

2. Number 30 of animals used in this study.

3. Species (common name) mice of animals used in the study.

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

Adult mice will be restrained manually by the nape of the neck. The abdomen will be swabbed with 70% ETOH. They will be prime by injecting 0.2 ml or less of pristane intraperitionally using a sterile 22g needle and a 1 cc syringe. After 7-14 days we will aseptically inject 0.5 ml of 5×10^5 to 5×10^6 hybridoma cells suspended in sterile PBS, IP using a 22g needle and a 1 cc syringe. Again the mouse will be restrained manually. Mice will be observed daily for ascitic fluid build up and for signs of disease or illness (see section VIII-A.B). Ascitic fluid may begin to build up within 1-2 weeks following injection of the cells. We will tap the fluid when the mouse is noticeably large, but before the mouse has difficulty moving. The mouse will be manually restrained and aseptically tapped using an 18g sterile needle attached to a 5 cc syringe. A mouse will not be tapped more than 3 times.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

This procedure is necessary for the production of monoclonal section antibodies against bovine cell components. Euthanasia will be performed on mice by animal caretakers when the following occurs; 1) the animal appears lethargic and fails to move about freely in the cage when stimulated; 2) appears more than 10% dehydrated, as determined by skin tone; 3) appears to be in discomfort, as evidenced by abnormal posturing, rough haircoat, etc.; 4) the circulation/hydration status of the animal appears to be impaired, as evidenced by abnormal mucous membrane color, poorly perfused extremities, etc. or following the final tap. Please see section IX.C for euthanasia details.

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_____ CFR_____

DEC 0 1 2003

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 in Section 2150.

51-F-0016

See reverse side for Additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FY 2003
ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. **REGISTRATION NO.** 51-F-016 Cust. ID 441

FORM APPROVED OMB NO. 0549-0036

2. **HEADQUARTERS RESEARCH FACILITY** (Name and Address, as registered with USDA, include zip code)

National Institutes of Health
Deputy Director for Intramural Research
31 Center Drive, Bldg 31, Room B1C37, MSC 2252
Bethesda , MD 20892

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)	
Composite includes: APF, CC, NCI, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIAID (RML), NIAMS, NICHD, NIDA, NIDCD,	NIDCR, NIDDK, NIEHS, NIMH, NINDS, ORS, VRC

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	17	41	187	0	128
5. Cats	14	24	43	0	67
6. Guinea Pigs	41	103	206	0	309
7. Hamsters	378	832	1019	55	1897
8. Rabbits	217	405	875	0	1280
9. Non-human Primates	1365	1268	872	16	2156
10. Sheep	44	26	50	0	76
11. Pigs	178	0	172	0	172
12. Other Farm Animals	--	--	--	--	--
Goats	0	0	0	0	0
Burro	0	0	0	0	0
Horses	1	0	0	0	0
Cattle	2	4	0	0	4
Chickens	1	2250	2080	0	4330
Turkeys	1	0	0	0	0

ASSURANCE STATEMENTS

1) Profesionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetic 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 regularions be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (ACUC). **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 adequecy 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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME AND TITLE OF C.E.O.	IAL (Type or print)	DATE SIGNED
			11/25/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88) which is obsolete)

DEC 0 1 2003

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 in Section 2150.

See reverse side for Additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FY 2003

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO.
2. 51-F-016 Cust. ID 441

FORM APPROVED
OMB NO. 0549-0036

3. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include zip code)

National Institutes of Health
Deputy Director for Intramural Research
31 Center Drive, Bldg 31, Room B1C37, MSC 2252
Bethesda , MD 20892

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 12 &/OR 13 OTHER (List by Species)	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)
12. Goose	0	0	0	0	0
Duck	0	0	0	0	0
13. Gerbils	3	0	3	0	3
Ferrets	0	0	0	0	0
Cotton Rats	0	135	0	0	135
Squirrels	110	16	296	0	312
Pigeons	0	25	0	0	25
Frogs	38	3458	1787	0	5245
Fish	1150	57283	1686	0	58969
Other Amphibians	8	0	16	0	16
Vole	64	0	0	0	0
Mink	100	15	0	0	15
Wild Mice	80	15	0	0	15
Llama	1	0	0	0	0
Chinchillas	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetic 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 (ACUC). **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 AND TITLE OF C	TIONAL OFFICIAL (Type or print)	DATE SIGNED
			11/25/03

APHIS FORM 7023A
(AUG 91)

Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study.

   55

3. Species (common name) of animals used in this study.

   Hamsters

4. Explain the procedure producing pain and/or distress, including reason(s) for species selected.

Leishmanial diseases are major parasitic diseases of man. The stage of the parasite that grows in the vertebrate host and causes disease cannot be generated in vitro. It can only be obtained from in vivo sources. In nature, most leishmanial species are maintained within animal reservoirs, usually rodents. Laboratory mice and hamsters, therefore, are an excellent source of intracellular parasites for in vitro study and serve as an ideal model to study the immunology of leishmanial disease. The mechanisms by which infected macrophages can be activated to kill the parasite will be explored. The number of animals proposed for use is the minimum number necessary to obtain statistically meaningful results.

The hamster is the only laboratory animal that becomes infected with visceral leishmaniasis. There is no way to test the action of vaccines in vitro. The whole animal is required to study complex immune responses and the outcome of infection. Information derived from the immune system responses being examined cannot be gathered by using cell culture or computer models.

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.

Visceral Leishmaniasis in hamsters causes hepatomegaly and anemia. The progression of visceral infection in hamsters is not associated with any overt pathology or changes in behavior until infection is severe, at which time hamsters begin to move slowly and lose their appetite. Infections are expected to progress in all hamsters used until the animals show signs of morbidity. The point of onset of morbidity is variable, but generally occurs in the period 6-10 weeks post infection. Disease is progressive and affected hamsters will have fever and chills as evidenced by shivering. Without intervention, over several weeks, affected hamsters will become cache tic, moribund, and eventually die. Infected hamsters will be closely monitored as soon as signs of morbidity are noted, laboratory preparations will ensue, to harvest organs and citrate the parasitic load. Laboratory preparations require several work days to complete. In all cases, hamsters showing signs of morbidity will be euthanized within one week of the onset of morbidity. All hamsters in a study group are generally euthanized within the period between 2 and 4 months post-inoculation.

Animal care and monitoring procedures will follow the NIH ARAC guideline, 'Endpoints in ASPs'. All infected animals will be monitored daily for appetite, normal level of activity, swelling, pain, and ulceration during the course of infection by NIAID ACB personnel and where necessary by the individual listed on this proposal performing the experiment. Once animal care or research personnel note signs of pain/distress, animals will be observed twice daily to include weekends and holidays.

Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study.

12 naimals under one protocol and 4 animals under another protocol.

3. Species (common name) of animals used in this study.

marmoset

4. Explain the procedure producing pain and/or distress, including reason(s) for species selected.

Protocol #1

The purpose of this research is to evaluate using clinical evaluations, MRI and histopathology, the proprietary Berlex human CCR5 receptor antagonist in the marmoset EAE model in order to establish its potential as a novel MS therapeutic. If successful in arresting or altering the EAE disease course in the marmoset, this study will then serve as a basis for translational clinical research studies in multiple sclerosis patients. CCR5 chemokine through the CCR5 receptor is thought to mediate the migration and stimulation of macrophages in autoimmune diseases such as MS. At this time, there are a limited number of therapies that have been shown to slow the crippling and debilitating disease of MS that primarily affects women from age 20-40 years. Despite these new treatments MS patients continue to have severe exacerbations of the disease resulting in a decline in their neurological function and quality of life. Preliminary treatment strategies in rodents occasionally can provide information concerning dose and efficacy, however, non-human primate studies provide essential data on dosing and safety that can be used for a clinical trial.

The marmoset has been chosen for these studies because it is characterized by a relapsing-remitting clinical course and by pathologic findings of peri-vascular inflammation, demyelination and astrogliosis similar to what is observed clinically in MS patients and is the best available model for the human disease. In contrast, the EAE model in cynomologous monkeys does not have relapsing-remitting episodes to the disease and is hemorrhagic in nature. EAE in rodent models are generally progressive and lesions are usually confined to the spinal cord. LDRR has been able to perform *in vivo* MR microscopic imaging in the EAE mouse model at 4.7 Tesla, however, this disease primarily occurs in the brain stem and spinal cord which is difficult to image due to size and location. The disease in rabbits has a relatively acute course that also has area of necrosis and hemorrhage and does not result in demyelinating lesions in the CNS. The disease in guinea pigs is primarily edematous and non-demyelinating. The drug we are testing in this study does not have adequate homology to rodents to permit a true evaluation of the drug in the SJL mouse EAE model. Berlex

cloned and expressed the human CCR5 receptor that has 91% homology with the r results indicate that several compounds have been shown to be ineffective against CR5 receptor partly because the mouse only shares about 80% homology with the 5 receptor. For this reason there exists a relative lack of cross reactivity of the human t compounds with the mouse CCR5 receptor and therefore these compounds are too low in y and selectivity to demonstrate efficacy in the EAE SJL mouse model or other rodent ms.

Protocol #2

The purpose of this research is to evaluate whether magnetically labeled encephalitogenic T-cells can induce EAE disease in the marmoset and whether these labeled cells can be detected by MRI using at clinically relevant field strength of 1.5 Tesla. By detecting the migration of the labeled cells into the brain in vivo, will allow for future studies investigating the effect of new therapies on the disease course and if the T-cell trafficking into the brain can be limited. In addition, specific types of T-cells (Th1 vs Th2) cells can be labeled and using MRI, it can be determined which population of cells modulates the disease.

The marmoset has been chosen for these studies because it is characterized by a relapsing-remitting clinical course and by pathologic findings of peri-vascular inflammation, demyelination and astrogliosis similar to what is observed clinically in MS patients and is the best available model for the human disease. In contrast, the EAE model in cynomologous monkeys does not have relapsing-remitting episodes to the disease and is hemorrhagic in nature. EAE in rodent models are generally progressive and lesions are usually confined to the spinal cord. LDRR has been able to perform *in vivo* MR microscopic imaging in the EAE mouse model at 4.7 Tesla, however, this disease primarily occurs in the brain stem and spinal cord which is difficult to image due to size and location. The disease in rabbits has a relatively acute course that also has area of necrosis and hemorrhage and does not result in demyelinating lesions in the CNS. The disease in guinea pigs is primarily edematous and non-demyelinating.

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.

We are submitting a column E listing for marmosets induced with EAE that may experience distress as a result of paresis or paralysis. Animals that have a clinical score of 5 to 10 (paralysis of hand&/or foot, paralysis of proximal and distal limb function- monoparesis, paralysis of two limbs- hemiplegia or paraplegia, paresis of all four limbs- quadriparesis, or paralysis of all four limbs- quadriplegia) will be listed as column E. The motor, sensory or visual deficits can be temporary or chronic depending on the extent of the disease or damage to white matter. The animal's enviroment is adapted to facilitate movement about the cage and access to food. Heat lamps or microwaveable packs are used for comfort in cases of loss of body heat due to EAE. Fluffy pads are used if the animal likes to lie on them. Mild analgesics will be given for lethargy. Special efforts will be taken to ensure that animals that have difficulty feeding will receive adequate amounts of food and water and that animals that develop neurological symptoms will be housed appropriately to minimize pain and distress. If, in the opinion of the attending veterinarian, an animal cannot be properly cared for or if the animal reaches euthanasia criteria, then the animal will be euthanized.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Alamogordo Primate Facility

1. REGISTRATION NO. 51-F-0016 CUSTOMER NO. 441

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)*

See Attached Listing
Holloman Air Force Base, Alamogordo, NM

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	281				–
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.

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)

OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/5/01

(Replaces VS), which is obsolete

PART 1 - HEADQUARTERS

(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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0016 CUSTOMER NO. 441

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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			42		42
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates			14		14
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.

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)

SIGNATUR	INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
			11/1/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0014 | CUSTOMER NO. 441 | FORM APPROVED OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)

See Attached Listing

NCI

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	0	28	5	0	33
5. Cats	0	0	36	0	36
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	3	411	0	414
9. Non-Human Primates	59	51	98	0	149
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Frogs	0	40	0	0	40

DFC 11/2

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/30/01

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0016 CUSTOMER NO. 441

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)*	
See Attached Listing NHGRI	

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					
Zebrafish		1330			1330

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 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)

SIGNATU

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

DATE SIGNED NOV 14 2001

h is obsolete

PART 1 - HEADQUARTERS

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 in Section 2150.

See reverse side for Additional information.

Interagency Report Control No. 0188-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
51-F-016 Cust Id 441

FORM APPROVED
OMB NO. 0549-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include zip code)

National Eye Institute
National Institutes of Health

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)	

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	10	0	36	0	36
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	58	0	0	58
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	211	0	211
9. Non-human Primates	18	0	72	0	72
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Profesionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetic 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 regularions be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (ACUC). 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 adequecy 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)

	NAME AND TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or print)	DATE SIGNED
		11/19/01

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
51-F-0016 Cust Id 441

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*
National Heart, Lung and Blood Institute
Division of Intramural Research
National Institutes of Health
9000 Rockville Pike, Bethesda, MD 20892

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)*

National Institutes of Health
Bethesda, MD 20892

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	12	0	61	0	61
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	16	0	16
7. Hamsters	0	0	0	0	0
8. Rabbits	15	0	156	0	156
9. Non-human Primates	130	0	164	0	164
10. Sheep	4	0	86	0	86
11. Pigs	0	0	97	0	97
12. Other Farm Animals					
13. Other Animals					
Fish	0	0	4	0	4

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
		11/13/01

APHIS FORM 7023
(AUG 91)

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

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 in Section 2150.

See reverse side for Additional information.

Interagency Report Control No. 0580-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

REGISTRATION NO. 51-F-0016 **CUSTOMER NO** 441

FORM APPROVED
OMB NO. 0579-0036

1. **HEADQUARTERS RESEARCH FACILITY** (Name and Address, as registered with USDA, include zip code)

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)	

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		22			22
7. Hamsters					
8. Rabbits		13	16		29
9. Non-human Primates		37	140		177
10. Sheep					
11. Pigs			19		19
12. Other Farm Animals					
Goat					
Chickens					
13. Other Animals					
Frogs		52			52

ASSURANCE STATEMENTS

1) Profesionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetic 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 regularions be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (ACUC). **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 adequecy 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)

AL OFFICIAL	NAME AND TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or print)	DATE SIGNED
		11/13/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88) which is obsolete)

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0016 | CUSTOMER NO. 441 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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		10			10
7. Hamsters					
8. Rabbits			19		19
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Xenopus		220			220
Bullfrog		20			20

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/13/01

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 in Section 2150

See reverse side for Additional information

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FY '01
ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. **REGISTRATION NO.** 51-F-0016 Cust Id 441

FORM APPROVED OMB NO. 0549-0036

2. **HEADQUARTERS RESEARCH FACILITY** (Name and Address, as registered with USDA, include zip code)

NIH/NIAID

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)	

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	10	165	32	0	197
7. Hamsters	13	467	287	0	754
8. Rabbits	0	154	0	0	154
9. Non-human Primates	304	1205	37	0	1242
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	--	--	--	--	--
Goat	0	1	0	0	1
Chickens	0	2145	0	0	2145
13. Other Animals	--	--	--	--	--
Gerbils	5	22	0	0	22
Cotton Rats	0	604	0	0	604
Frogs	0	14	8	0	22

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetic 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 (ACUC). **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 AND TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or print)	DATE SIGNED
		11/2/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0016 CUSTOMER NO. 441

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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.) NIH/NIAID/ROCKY MOUNTAIN LABORATORIES, Hamilton, Montana

FACILITY LOCATIONS*(sites)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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		14			14
7. Hamsters	289	18	360		378
8. Rabbits		37			37
9. Non-Human Primates	61				
10. Sheep		2			2
11. Cattle		3			3
12. Other Farm Animals					
Mink	27	93			93
13. Other Animals					
Microtus (vole)	41				
Wild Mice(peromyscus)	70	62			62

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/20/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0016 | CUSTOMER NO. 441 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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		2	26		28
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Fish		2310	11		2321

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 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)

IAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/9/01

:3 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

(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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0016 CUSTOMER NO. 441

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	0	0		0
5. Cats	0	0	0		0
6. Guinea Pigs	0	13	0		13
7. Hamsters	0	0	0		0
8. Rabbits	0	18	40		58
9. Non-Human Primates	0	595	31		626
10. Sheep	0	0	0		0
11. Pigs	0	0	0		0
12. Other Farm Animals	0	0	0		0
13. Other Animals					
Xenopus Laevis	0	1982	36		2018
Xenopus Tropicalis	0	41	0		41
Zebrafish	0	55275	0		55275

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 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)

SI	L	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
			11/8/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0016 CUSTOMER NO. 441

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)*

See Attached Listing

NIH/NIDA/IRP Baltimore, Maryland

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-Human Primates	40	40	46	0	86
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Pigeons	0	6	0	0	6
13. Other Animals					
Frogs	13	0	26	0	26

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 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	AL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
			11/7/01

APHIS FORM 7023 (AUG 91)

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

PART 1 - HEADQUARTERS

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 in Section 2150.

See reverse side for Additional information.

Interagency Report Control No. 0580-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FY '01

ANNUAL REPORT OF RESEARCH FACILITY

NIDCR Veterinary Resources Core

1. REGISTRATION NO.	FORM APPROVED
51-F-016	OMB NO. 0549-0036

2. **HEADQUARTERS RESEARCH FACILITY** (Name and Address, as registered with USDA, include zip code)

NIH/NIDCR

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)	

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	6	12	0	18
7. Hamsters	0	0	0	0	0
8. Rabbits	0	12	0	0	12
9. Non-human Primates	20	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	--	--	--	--	--
Goat	0	0	0	0	0
Chickens	0	0	0	0	0
13. Other Animals	--	--	--	--	--
	--	--	--	--	
	--	--	--	--	
Gerbils	0	0	0	0	0

ASSURANCE STATEMENTS

1) Profesionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetic 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 regularions be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (ACUC). **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 adequecy 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)

	NAME AND TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or print)	DATE SIGNED
L		10/31/01

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

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0016 CUSTOMER NO. 441

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	24	0	24
9. Non-Human Primates	0	0	22	0	22
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Xenopus	0	0	57	0	57
Bullfrogs	12	0	0	0	
Dendrobatid frogs		3	0	0	3

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-6-01

FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

This report is required by law (7 USC 2143). Failure to report according to the regulations may result in a notice to cease and desist and to be subject to penalties as provided for in Section 2150. additional information. 0150-0001-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0016 | CUSTOMER NO. 441 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH /ORS/VRP
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	3		5		5
5. Cats	1				
6. Guinea Pigs	576	4			4
7. Hamsters					
8. Rabbits					
9. Non-Human Primates		13			13
10. Sheep	34				
11. Pigs	28				
12. Other Farm Animals					
13. Other Animals					
Goats	4				
Llama	1				
Bovine	3				

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 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)

bove is true, correct, and complete (7 U.S.C. Section 2143)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)* | DATE SIGNED NOV 09 2004

hich is obsolete

PART 1 - HEADQUARTERS

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 2150. additional information. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 51-F-0016 CUSTOMER NO. 441

FORM APPROVED
OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL INSTITUTE OF HEALTH /ORS/VRP
BLDG. 31, ROOM B1C37, MSC 2252
9000 ROCKVILLE PIKE
BETHESDA, MD 20892
(301) 496-5424

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Burro	1				
Horse	1				
Chicken	1				
Turkey	1				
Duck	1				
Goose	1				

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

APHIS FORM 7023A (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

NOV 30 2004

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 in Section 2150.

See reverse side for Additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FY 2004

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-016 Cust. ID 441

FORM APPROVED OMB NO. 0549-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include zip code)

National Institutes of Health
Deputy Director for Intramural Research
31 Center Drive, Bldg 31, Room B1C37, MSC 2252
Bethesda , MD 20892

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)	
Composite includes: APF, CC, NCI, NEI, NHGRI, NHLBI, NIA, NIAAA, NIAID, NIAID (RML), NIAMS, NICHD, NIDA, NIDCD,	NIDCR, NIDDK, NIEHS, NIMH, NINDS, ORS, VRC

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	18	48	307	0	355
5. Cats	0	39	18	0	57
6. Guinea Pigs	7	366	160	1	527
7. Hamsters	224	874	561	0	1435
8. Rabbits	7	561	1196	0	1757
9. Non-human Primates	884	1412	998	23	2433
10. Sheep	0	51	45	0	96
11. Pigs	123	58	302	0	360
12. Other Farm Animals	--	--	--	--	--
Goats	0	0	0	0	0
Burro	0	0	0	0	0
Horses	0	0	0	0	0
Cattle	0	4	0	0	4
Chickens	0	1238	1560	0	2798
Turkeys	0	1	0	0	1

ASSURANCE STATEMENTS

1) Profesionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetic 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 (ACUC). **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)

NAME AND TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or print)	DATE SIGNED
	11/23/04

which is obsolete)

EXPLANATION FOR COLUMN E LISTING

This form will be sent to the USDA as part of the NIH Annual Report (USDA VS Form 7023) supporting all Column E Listings (procedures considered to produce more than momentary pain or distress without the administration of appropriate and adequate anesthetic, analgesic, or tranquilizer drugs.

Registration Number: **51-F-0016**
ICD: **NIAID**
Species: **Cotton Rats**
Number: **11**

Explain the procedure producing pain/or distress, including reason (s) for species selected.

Varicella-zoster virus (VZV) causes chickenpox in children, becomes latent in the dorsal root ganglia, and is reactivated decades later causing shingles (zoster) in adults. We are trying to develop a small animal model to induce reactivation of VZV. We will treat animals (cotton rats or rats) with immunosuppressive medication and then the animals will undergo hyperthermia treatment to induce reactivation. This procedure has been successful for reactivation of herpes simplex virus in animals, but has not been tried for VZV.

Animals will be inoculated with VZV i.m., immunosuppressed, and then undergo hyperthermia therapy. Hyperthemia treatment will consist of putting the animals in plastic tubes with air holes at the top and incubating the tubes in a water bath 43°C for 10 minutes. Thereafter animals will be dried if necessary and placed under a heating lamp for 10-30 min (to prevent hypothermia), before being returned to their cages. Animals will be observed every 10 minutes during recovery from hyperthermia. If the animal has not recovered by 60 minutes, it will be euthanized.

Cotton rats or rats are chosen because a model has been established for central nervous system infection by VZV with latency in these animals

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.

Anesthesia is not given during hyperthermia since it may reduce the likelihood of survival with hyperthermia, and since the established protocols using hyperthermia to induce reactivation of other viruses (e.g. Sawtell and Thompson, Journal of Virology 66:2150, 1992) do not use anesthesia during hyperthermia. Opioid analagesics may affect the results of the experiment by binding to the receptors on neurons and interfere with reactivation of the virus from neurons. Non-steroidal anti-inflammatory drugs cannot be used as they may have effects on the immune response to VZV and thus influence reactivation from latent infection.

EXPLANATION FOR COLUMN E LISTING

This form will be sent to the USDA as part of the NIH Annual Report (USDA VS Form 7023) supporting all Column E Listings (procedures considered to produce more than momentary pain or distress without the administration of appropriate and adequate anesthetic, analgesic, or tranquilizer drugs.

Registration Number: **51-F-0016**
ICD: **NIAID**
Species: **Guinea Pigs**
Number: **1**

Explain the procedure producing pain/or distress, including reason (s) for species selected.

Initial experiments could find that the degree of immunosuppression of guinea pigs with the highest dose of the immunosuppressive drugs in the NIH animal facility leads to bacterial infections that are not expected from the published data. If adverse effects are observed, further studies will be performed at lower doses of immunosuppressive drugs.

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.

Unanticipated bacterial superinfection could occur due to differences in the gastrointestinal and oropharyngeal flora or differences in airborne bacteria, the usual sources of bacterial infections following cyclophosphamide and triamcinolone treatment. In this event, we will need to amend the protocol and decrease the dose or duration of immunosuppression. With the desired degree of immunosuppression, animals will not become ill from either *C. glabrata* or bacterial superinfection. It is during this initial period that up to five guinea pigs might become unexpectedly ill. Once their illness is noted, euthanasia will be used. Guinea pigs that are killed before the end of the experiment cannot be used for determining response to therapy because treatment duration will be truncated.

EXPLANATION FOR COLUMN E LISTING

This form will be sent to the USDA as part of the NIH Annual Report (USDA VS Form 7023) supporting all Column E Listings (procedures considered to produce more than momentary pain or distress without the administration of appropriate and adequate anesthetic, analgesic, or tranquilizer drugs.

Registration Number: **51-F-0016**
ICD: **NIAID**
Species: **Aotus sp**
Number: **21**

Brief description of project including reason(s) for species selected:

Malaria is one of the most important infectious diseases affecting mankind. One third of the world's population is at risk of infection with malaria. Over 500 million people are infected each year. Over 2 million people die and most deaths are in children under five years of age. This parasite is rapidly developing resistance to most anti-malarial drugs. An effective vaccine is urgently needed.

The malaria parasites which infect humans will also infect gorillas, chimpanzees and a limited number of New World sub human primates including owl (Aotus) monkeys and squirrel (Saimiri) monkeys. The Aotus monkey model has been shown to be the most reasonable and productive for use in studies involving the most important human malaria, *Plasmodium falciparum.*

Animal models for human malaria vaccine efficacy are an important part of development and testing of prototype human malaria vaccines. In part this necessity derives from the fact that *in vitro* methods cannot perfectly or reproducibly duplicate the complex immunologic responses of animals or humans to vaccines. Evaluation of malaria parasite antigens as potential vaccines and therapeutic interventions requires the use of live animals because we currently lack a reliable *in vitro* correlate of protection and/or sequestration. If we can validate the *in vitro* models currently under development, then, at least some aspects of vaccine development (e.g., to study binding of parasites to adhesion molecules *in vitro,)* may be done *in vitro.* Ultimately, however, for the foreseeable future formulations destined for human clinical trials require testing in animal models.

Explanation of unrelieved pain or distress:

Animals on this study will receive Complete Freund's Adjuvant (CFA). Animals given CFA will likely develop granulomatous skin lesions. When these occur, animals will be monitored at least twice a day for lethargy, diarrhea, rough hair coat, absence of eating and/or drinking, other clinical signs, and the status of the skin lesions. Skin lesions will be kept clipped and cleaned.

These granulomatous skin lesions may occasionally lead to more serious conditions, such as peritonitis, pleuritis or other lesions due to migration of the CFA into body cavities or other areas. In animals that develop clinical signs indicative of these possible sequellae, diagnostic testing will be performed to rule out anemia, parasitemia or spontaneous disease, all of which are treatable as discussed in Part F. of the ASP. If moribundity occurs or serious conditions are diagnosed related to the CFA injections, such as peritonitis, these will be treated with appropriate treatments (such as drainage and antibiotics) or the animal will be euthanized.

For immunization-challenge studies in non-human primates, CFA is the gold standard against which all other adjuvants must be measured. Vaccine trials at the NIH and in other laboratories have been using CFA for decades in the evaluation of malaria vaccine candidates. There is no question that CFA is a less than satisfactory adjuvant. . One purpose of the trials that we conduct here at NIH and we collaborate on with other investigators at the CDC, is to evaluate alternatives to CFA with the hope of one day removing the need for its use in testing vaccine candidates.

Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 51-F-0016

2. Number of animals used under Column E conditions in this study.

two

3. Species (common name) of animals used in this study.

marmoset

4. Explain the procedure producing pain and/or distress, including reason(s) for species selected.

The purpose of this research is to evaluate whether magnetically labeled encephalitogenic T-cells can induce EAE disease in the marmoset and whether these labeled cells can be detected by MRI using at clinically relevant field strength of 1.5 Tesla. By detecting the migration of the labeled cells into the brain in vivo, will allow for future studies investigating the effect of new therapies on the disease course and if the T-cell trafficking into the brain can be limited. In addition, specific types of T-cells (Th1 vs Th2) cells can be labeled and using MRI, it can be determined which population of cells modulates the disease.
The marmoset has been chosen for these studies because it is characterized by a relapsing-remitting clinical course and by pathologic findings of peri-vascular inflammation, demyelination and astrogliosis similar to what is observed clinically in MS patients and is the best available model for the human disease. In contrast, the EAE model in cynomologous monkeys does not have relapsing-remitting episodes to the disease and is hemorrhagic in nature. EAE in rodent models are generally progressive and lesions are usually confined to the spinal cord. LDRR has been able to perform *in vivo* MR microscopic imaging in the EAE mouse model at 4.7 Tesla, however, this disease primarily occurs in the brain stem and spinal cord which is difficult to image due to size and location. The disease in rabbits has a relatively acute course that also has area of necrosis and hemorrhage and does not result in demyelinating lesions in the CNS. The disease in guinea pigs is primarily edematous and non-demyelinating.

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.

We are submitting a column E listing for marmosets induced with EAE that may experience distress as a result of paresis or paralysis. Animals that have a clinical score of 5 to 10 (paralysis of hand&/or foot, paralysis of proximal and distal limb function- monoparesis, paralysis of two limbs- hemiplegia or paraplegia, paresis of all four limbs- quadriparesis, or paralysis of all four limbs- quadriplegia) will be listed as column E. The motor, sensory or visual deficits can be temporatry or chronic depending on the extent of the disease or damage to white matter. The animals enviroment is adapted to facilitate movement about the cage and access to food. Heat lamps or microwaveable packs are used for comfort in cases of loss of body heat due to EAE. Fluffy pads

are used if the animal likes to lie on them. Mild analgesics will be given for lethargy. Special efforts will be taken to ensure that animals that have difficulty feeding will receive adequate amounts of food and water and that animals that develop neurological symptoms will be housed appropriately to minimize pain and distress. If, in the opinion of the attending veterinarian, an animal cannot be properly cared for or if the animal reaches euthanasia criteria, then the animal will be euthanized.

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 21!

See attached form for additional information. DEC 02 2004

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-F-0019
CUSTOMER NUMBER: 452

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Edgewood Chemical Biological Center
Bldg E3150
ATTN: AMSRD-ECB-RT-TV
Aberdeen Proving Ground, MD 21010-5424

Telephone: 410-436-8653

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		50	14	64	128
7. Hamsters					
8. Rabbits		133	14	279	426
9. Non-human Primates					
10. Sheep					
11. Pigs		0	0	60	60
12. Other Farm Animals					
13. Other Animals					
Mice		57	12	93	162
Rats		474	191	88	753
Fish		90	0	390	480

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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)

S | E & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)* | DATE SIGNED

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

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-F-0019

2. Number 8(mice)/88(rats)/50(rabbits)/60(pigs)/64(guinea pigs) of animals used in this study.

3. Species (common name) mice/rats/rabbits/pigs/guinea pigs of animals used in the study.

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

Eight (8) mice, eighty-eight (88) rats, fifty (50) rabbits, sixty (60) mini-pigs, and sixty-four (64) guinea pigs were used to test militarily unique compounds via the inhalation and oral route to establish relative importance of exposure concentration and duration on the probability of toxic and lethal responses. Historically, in studies designed to generate lethal dose-response curves, it has been assumed that approximately half of the exposed animals would be expected to die and that this level of response may potentially be associated with pain, discomfort, and/or distress.

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)

For these studies, the use of anesthetic/analgesic drugs during exposure may compromise the results of the proposed studies due to the fact that this class of compound may alter the respiratory minute volume and thus the dose of test compound that the animal receives. In addition, the expression of toxic signs may be altered by such treatment. Clement and Coperman (1984) suggest that chemical agent-induced convulsion and death are not necessarily associated with pain. Clement and Coperman (1984) have reported that Soman and Sarin induce a long-lasting naloxone-reversible analgesia in mice, which was not due to physical incapacitation.

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_____ CFR_____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-F-0019

2. Number 229 (rabbits) / 85 (mice) of animals used in this study.

3. Species (common name) rabbits / mice of animals used in the study.

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

Two hundred twenty-nine (229) rabbits and eighty-five (85) mice were tested with previously untested chemicals of military interest. The materials were tested intravenously in mice and both intravenously and dermally in rabbits.

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)

Animals that either died or suffered convulsive seizures during the test – these severe toxic signs could not be alleviated so that accurate test data could be collected. The data collected were important for several reasons: 1) to establish the toxicological profile of the chemical; 2) establish data to be used for human estimates; 3) establish data from which therapy/phophylaxix could be established; and 4) data would be included in material safety data sheets as a warning to potential users or in support to chemical staff in case of accidential exposures.

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 _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-F-0019

2. Number 390 of animals used in this study.

3. Species (common name) fish of animals used in the study.

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

Three hundred ninety (390) fish were exposed to 48-hour static (no water Changes) range-finding toxicity tests.

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)

Operculum movement is impaired with anesthetics, nullifying one of the experimental endpoints. Impairing the animal with an anesthetic may increase the effects of the toxicity challenge. Distress and pain are difficult, if not impossible, to judge with aquatic species due to the inability to observe vital signs that are readily obvious in terrestrials.

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_____ CFR_____

NOV 30 2004

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 in Section 2150.

See reverse side for Additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FY 2004

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **REGISTRATION NO.**
2. **51-F-016 Cust. ID 441**

FORM APPROVED
OMB NO. 0549-0036

3. **HEADQUARTERS RESEARCH FACILITY** (Name and Address, as registered with USDA, include zip code)

National Institutes of Health
Deputy Director for Intramural Research
31 Center Drive, Bldg 31, Room B1C37, MSC 2252
Bethesda , MD 20892

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 12 &/OR 13 OTHER (List by Species)	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, aualgesic, 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)
12. Goose	0	0	0	0	0
Duck	0	0	0	0	0
13. Gerbils	8	0	0	0	0
Ferrets	0	0	0	0	0
Cotton Rats	0	0	227	11	238
Squirrels	110	16	296	0	312
Pigeons	0	8	0	0	8
Frogs	0	0	0	0	2550
Fish	0	0	0	0	50224
Other Amphibians	0	0	0	0	95
Vole	9	0	0	0	0
Mink	0	85	0	0	85
Wild Mice	29	0	0	0	0
Llama	1	0	0	0	0
Chinchillas	0	0	29	0	29

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetic 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 (ACUC). **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 AND TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or print)	DATE SIGNED
		11/23/04

APHIS FORM 7023A
(AUG 91)

EG

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0021 **CUSTOMER NO.** 728

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNITED STATES ARMY MEDICAL RESEARCH
BLDG. 1425 FT. DETRICK
FREDERICK, MD 21702

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)*

INSTITUTE OF INFECTIOUS DISEASE
FREDERICK, MD 21702

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	618	251	157	913	1321
7. Hamsters		131	720	629	1480
8. Rabbits		176	37	292	505
9. Non-Human Primates	57	208	158	166	532
10. Sheep		35			35
11. Pigs					
12. Other Farm Animals					
Goats		101			101
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/19/2004

APHIS FORM 7023 **(AUG 91)**

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

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 51-F-0021 **CUSTOMER NO.** 728

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNITED STATES ARMY MEDICAL RESEARCH
BLDG. 1425 FT. DETRICK
FREDERICK, MD 21702

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Horses	5	2			2

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/19/2004

APHIS FORM 7023A (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

Animal Care
The Reasons We Care

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
(APHIS)

Instructions | Submit Form 7023A

FY2004 APHIS FORM 7023A Submission

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 2150.

See below for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE **ANNUAL REPORT OF RESEARCH FACILITY** *(TYPE OR PRINT)*	**1. Registration No:** 51-F-0021 / 728	FORM APPROVED OMB NO. 0579-0036
	2. Headquarters Research Facility *(Name and Address, as registered with USDA, include Zip Code)*: UNITED STATES ARMY MEDICAL RESEARCH BLDG. 1425 FT. DETRICK FREDERICK, MD 21702 T: (301) 619-4708	

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY View Column Definitions

A	B	C	D	E	F
12. Other Farm Animals Goats	0	101	0	0	101
12. Other Farm Animals Horses	5	2	0	0	2
Select One	0	0	0	0	0
Select One	0	0	0	0	0
Select One	0	0	0	0	0
Select One	0	0	0	0	0
Select One	0	0	0	0	0
Select One	0	0	0	0	0
Select One	0	0	0	0	0

DEC 02 2004

Animal Care
The Reasons We Care

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
(APHIS)

Instructions | Checklist | Submit Form 7023

FY2004 APHIS FORM 7023 Submission

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 2150.

See below for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE **ANNUAL REPORT OF RESEARCH FACILITY** *(TYPE OR PRINT)*	**1. Registration No:** 51-F-0021 / 728	FORM APPROVED OMB NO. 0579-0036
	2. Headquarters Research Facility *(Name and Address, as registered with USDA, include Zip Code)*: UNITED STATES ARMY MEDICAL RESEARCH BLDG. 1425 FT. DETRICK FREDERICK, MD 21702 T: (301) 619-4708	

3. Reporting Facility (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Please verify that all Sites are listed below. To list additional Sites, select the link below.)

FACILITY LOCATIONS *(sites)* **List Additional Sites**

3a. INSTITUTE OF INFECTIOUS DISEASE VETERINARY MEDICAL DIVISION BLDG. 1425 FT. DETRICK FREDERICK, MD 21702	3b.
3c.	3d.

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY View Column Definitions

A	B	C	D	E	F
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	618	251	157	913	1321
7. Hamsters	0	131	720	629	1480
8. Rabbits	0	176	37	292	505
9. Non-Human Primates	57	208	158	166	532
10. Sheep	0	35	0	0	35
11. Pigs	0	0	0	0	0
12. Other Farm	Use APHIS Form 7023A				

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 51-F-0021

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

Guinea Pigs (913)
Rabbits (292)
Hamsters (629)
Non-Human Primates (166)

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

The mission of the United States Army Institute of Infectious Diseases is to perform studies on the pathogenesis, diagnosis, prophylaxis, treatment and epidemiology of infectious diseases for medical defense against potential biological threat agents and naturally occurring infectious agents and toxins of military importance that require special containment. The animals listed in column E have all been used in some aspect of these studies. The rational and justification for the use of animals in each of the studies performed in support of the institute's mission have been closely scrutinized by the IACUC and the Institute's leadership. The nature of most infectious diseases and toxins studied at USAMRIID involves a clinical course, which includes some degree of discomfort (e.g. fever, myalgia, etc.).

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)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case-by-case basis by the IACUC.

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: N/A
CFR:

Optional Column E Explanation Form

1. Registration Number: 51-F-021 / 728

2. Number 166 **of animals used in this study.**

3. Species (common name) Non-human Primates **of animals used in this study.**

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

Nonhuman primates used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

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 question 6 below)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

2. **Number** 913 **of animals used in this study.**

3. **Species** (common name) Guinea Pigs **of animals used in this study.**

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

Guinea pigs used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

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 question 6 below)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

2. **Number** 629 **of animals used in this study.**

3. **Species** (common name) Hamsters **of animals used in this study.**

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

Hamsters used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection.
c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

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 question 6 below)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

Optional Column E Explanation Form

1. Registration Number: 51-F-021 / 728

2. Number 292 **of animals used in this study.**

3. Species (common name) Rabbits **of animals used in this study.**

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

Rabbits used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection.
c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

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 question 6 below)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

Animal Care
The Reasons We Care

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
(APHIS)

FY2004 APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-F-0021 / 728

2. Species (common name) of animals used in the study:
(check all that apply for this explanation)
- ☑ Guinea Pigs
- ☑ Hamsters
- ☑ Rabbits
- ☑ Non-Human Primates

3. Number of animals used in this study: (Generated By System)

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

The mission of the United States Army Institute of Infectious Diseases is to perform studies on the pathogenesis, diagnosis, prophylaxis, treatment and epidemiology of infectious diseases for medical defense against potential biological threat agents and naturally occurring infectious agents and toxins of military importance that require special containment. The animals listed in column E have all been used in some aspect of these studies. The rational and justification for the use of animals in each of the studies performed in support of the institute's mission have been closely scrutinized by the IACUC and the Institute's leadership. The nature of most infectious diseases and toxins studied at USAMRIID involves a clinical course, which includes some

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)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case-by-case basis by the IACUC.

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):

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
(APHIS)

FY2004 APHIS Form 7023 Submission Assurance Statements and Signature Submission

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

Registration No:	51-F-0021 / 728
Headquarters Research Facility:	UNITED STATES ARMY MEDICAL RESEARCH BLDG. 1425 FT. DETRICK FREDERICK, MD 21702 T: (301) 619-4708

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 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	**Name & Title of C.E.O. or Institutional Official**	**Date Signed:**
		10 /19/2004

Submit

SUMMARY OF IACUC APPROVED EXCEPTIONS:

Brief Description of Exception	Species of Animal	Number of Animal
Deviation of sanitization procedures as outlined in the AWA. Animals are in a BL3 and BL4 biocontainment area that does not allow routine cage sanitizing in the cagewash facility at the required two week inteval due to safety concerns and logistical constraints. Cages are sanitized in place until it is no longer possible to adequately clean them by hand at which time they are replaced with mechanically sanitized cages.	Nonhuman Primate	288
	Rabbits	246
	Guinea Pigs	983

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150. additional information. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
51-F-023 # 530

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

11-30-2001 RCVD

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

MPN-4, HFV-4
Center for Veterinary Medicine
Food and Administration
7519 Standish Place; Rockville, MD 20855

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)*

12709 Twinbrook Parkway; Office of Science and Technology; HFZ-100; Rockville, MD 20879

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	0	6	0	0	6
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. Yes.

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

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.
Yes, no exceptions to 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. Yes.

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
		11/28/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

12-05-2001 RCVD

1. REGISTRATION NO. 51-F-0026 CUSTOMER NO. 12782

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

CENTER FOR VETERINARY MEDICINE
7500 STANDISH PLACE
ROCKVILLE, MD 20855
(301) 827-4172

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)*

8401 Muirkirk Rd
Laurel, MD 20708

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		42			42
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep		34			
11. Pigs			68		68
12. Other Farm Animals					
Poultry	250	350			350
13. Other Animals					
Cattle	10	3			3
Fish.	3	97	1130		1227

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/27/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 55-F-0001 **CUSTOMER NO.** 962

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

U.S. ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH & ENVIRONMENTAL
RESEARCH LAB (MAIL DROP 51)
RESEARCH TRIANGLE PA, NC 27711
(919) 541-2281

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)*

See Attached Listing

11-23-2001 RCVD

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	None	6	None	None	6
5. Cats	None	None	None	None	0
6. Guinea Pigs	None	None	93	None	93
7. Hamsters	None	133	None	None	133
8. Rabbits	None	23	None	None	23
9. Non-Human Primates	None	None	None	None	0
10. Sheep	None	None	None	None	0
11. Pigs	None	None	None	None	0
12. Other Farm Animals	None	None	None	None	0
13. Other Animals	None	None	None	None	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, 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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-16-01

APHIS FORM 7023 (AUG 91)

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

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 55-F-0001
Customer Number: 962
Facility: U.S. ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH & ENVIRONMENTAL
RESEARCH LAB (MAIL DROP 51)
RESEARCH TRIANGLE PA, NC 27711
(919) 541-2281

U.S. ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH & ENVIRONMENTAL
RESEARCH LAB (MAIL DROP 51)
RESEARCH TRIANGLE PA, NC 27711

This report is required by law (7 USC 2143). Failure to report according to the regulations can sult in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 55-F-0007 **CUSTOMER NO.** 955

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

SPECIAL OPP MEDICAL TRAINING BN
BLDG 5--3845
KEDENBURG RD
FORT BRAGG, NC 28310-5200

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)*

US ARMY, ADAMS
FORT BRAGG, NC 28310-5200

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			500		500
9. Non-Human Primates					
10. Sheep			2		2
11. Pigs			63		63
12. Other Farm Animals					
Goats			1629		1629
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/29/2001

APHIS FORM 7023 **(AUG 91)** **(Replaces VS FORM 18-23 (Oct 88), which is obsolete**

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 55-F-0007 | CUSTOMER NO. 955 | FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

SPECIAL OPP MEDICAL TRAINING BN
BLDG 5--3845
KEDENBURG RD
FORT BRAGG, NC 28310-5200

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Chickens			500		500

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/29/2001

APHIS FORM 7023A (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

This report is required by law (7 USC 2143). Failure to report according to the regulations can

JAN 22 2002

See attached form for additional information

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 57-F-0003

CUSTOMER NUMBER: 948

FORM APPROVED
OMB NO. 0579-0036

Dept. Clinical Investigation
Dwight David Eisenhower Amc
Fort Gordon, GA 30905

Telephone: (999) -999-9999

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

Bldg. 38705, DDEAMC FT Gordon FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	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, a	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	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	2	0	21	0	21
9. Non-human Primate	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	17	0	17
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, 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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print*	DATE SIGNED
		01-16-0

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 57-F-0004 | CUSTOMER NO. 947 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

CTR. FOR DISEASE CNTL. & PREV.
1600 CLIFTON ROAD, NE MSG-28
ATLANTA, GA 30333
(404) 639-1320

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)*

~~See Attached Listing~~ NIOSH, Morgantown, WV 26505
DVBD, Foothills Campus, Ft. Collins, CO 80522
Chamblee Research Animal Section
4770 Buford Hwy, Bg. 15, Chamblee, GA 30341
Clifton Road Research Animal Section
1600 Clifton Rd NE, Bg 6/15, Atlanta, GA 30333
Lawrenceville Research Animal Section
602 Webb Gin House Rd, Lawrenceville, GA 30045

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	0	28	0	0	28
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	758	15	773
7. Hamsters	13	0	165	0	165
8. Rabbits	9	46	178	47	271
9. Non-Human Primates	37	4	704	55	763
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Cows	0	0	4	0	4
13. Other Animals					
Baboons	2	0	0	0	0
Chimpanzees	0	0	21	0	21
Ferrets	66	82	221	42	345

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/29/01

APHIS FORM 7023 (AUG 91) (Replaces US FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 57-F-0004 | CUSTOMER NO. 947

FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

CTR. FOR DISEASE CNTL. & PREV.
1600 CLIFTON ROAD, NE MSG-28
ATLANTA, GA 30333
(404) 639-1320

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Gerbils	15	0	5	0	5
Goats	0	0	2	0	2
Horse	0	2	0	0	2
Mongoose	0	1	11	4	16
Mouse, White Footed	0	24	132	0	156
Mouse, Meadow	0	0	20	0	20
Mouse, pine	7	0	28	10	38
Raccoon	0	12	8	0	20
Rat, Cotton	14	24	64	8	96
Skunk	12	0	0	0	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, 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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/29/01

November 20, 2001

Centers for Disease Control and Prevention
Atlanta, Georgia - Registration number 57-F-0004

Column E explanations for USDA, APHIS form 7023:

The research protocols on two of the ferrets (#1010) and four of the mongoose (#1140) reported in column E were all part of ongoing rabies studies. Anesthetics and/or analgesics were used for routine veterinary procedures as needed. The animals were challenged with a live rabies virus to determine the efficacy of the vaccine, the virulence of the virus, or the pathophysiology of the disease in that species. Those which developed clinical signs of rabies were euthanized to prevent progression of disease past the point of confirmed diagnosis. Most animals were actually in pain category D, but because a few animals died acutely from the disease they were placed in category E.

The 40 ferrets reported on protocol #1077 were used in studies involving H5N1 influenza viruses. Infection of humans with H5N1 viruses resulted in a 33% mortality rate. If the ferret is to be a useful model for infection with these viruses, it is important to determine if it reacts similarly when infected. Based on serological studies, where some unexpected deaths were observed in H5N1 virus infected ferrets, we expect that 10 - 30% of animals may develop severe disease and/or death from infection of highly pathogenic avian H5 viruses. Any animals that were found in a moribund state (near death and are not expected to recover), were euthanized.

Six of the primates on protocol # 1186 were used in malaria studies for which the immunogenicity and efficacy of potential vaccines were tested using Freund's adjuvant.

One rabbit on protocol #1089 was used to obtain hyperimmune serum to schistosomiasis using Freund's adjuvant. The serum produced will be compared to other hyperimmune serum produced with other adjuvants.

Forty-six rabbits were used on protocol #1190 for the production of hyperimmune serum against smallpox. Four of these rabbits received Freund's adjuvant. The remainder were inoculated with smallpox vaccine viruses to produce the immune serum. Because of the nature of the pox lesions and the Freund's lesions, all of these animals were placed in category E. Analgesics were administered as necessary.

Twenty nonhuman primates (#1188) and six nonhuman primates (#1195) were used for safety studies of new smallpox vaccines being developed. Anesthetics and analgesics were used as necessary. None of the animals were reported with problems secondary to the studies but because these studies were being conducted at contract facilities and because there was a potential for encephalitis secondary to the studies, we placed all animals in category E.

Twenty-three nonhuman primates were used in studies of pathogenicity of the smallpox virus. Appropriate anesthetics and analgesic were used for procedures during the study. When animals met the criteria for "terminally ill" (such as: progressive state of depression, recumbency, inappropriate responses to external stimuli, forced abdominal respiration and dyspnia) they were humanely euthanized.

Eight cotton rats (#1167) and 10 pine mice (#1169) were used in pathogenic studies of Rickettsia rickettsii. Most of the animals in these studies did not show clinical illness and were reported in pain category D. However, since these animals did exhibit signs of serious disease, they were reported in category E.

Fifteen guinea pigs (#1126) were utilized to study the pathogenesis of Mycobacterium ulcerans. Though these animals were treated with appropriate analgesics as needed, they were placed in category E due to the nature of the agent and disease progression.

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 2150.

See below for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

Centers for Disease Control and Prevention
Atlanta, GA; Ft. Collins, CO; Morgantown, WV

1. CERTIFICATE NUMBER:
57-F-0004
CUSTOMER NUMBER: 947

FORM APPROVED
OMB NO. 0579-0036

Centers for Disease Control and Prevention
1600 Clifton Road NE
Mailstop C-17
Atlanta, GA 30333
Telephone (404)639-2462

DEC 01 2004

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)* - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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 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	24	0	34	0	34
5. Cats	0	0	4	0	4
6. Guinea Pigs	0	54	714	0	768
7. Hamsters	57	0	637	198	835
8. Rabbits	22	4	318	34	356
9. Non-Human Primates	51	0	661	70	731
10. Sheep	0	0	0	0	0
11. Pigs	0	0	19	0	19
12. Other Farm Animals	Use APHIS Form 7023A				
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.

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	Name & Title of C.E.O. or Institutional Official	Date Signed:
		11/30/2004

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 2150.

See below for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. Registration No: 57-F-0004 / 947

FORM APPROVED
OMB NO. 0579-0036

2. Headquarters Research Facility *(Name and Address, as registered with USDA, include Zip Code)*:

Centers for Disease Control and Prevention
1600 Clifton Road NE
Mailstop C-17
Atlanta, GA 30333
Telephone (404)639-2462

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ***(Attach additional sheets if necessary or use this form.)***

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 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)
Agouti	0	0	4	0	4
Bat	12	0	188	9	197
Chicken	0	0	58	0	58
Chinchilla	0	0	1	0	1
Chipmunk	0	78	55	0	133
Coatimundi	0	0	16	0	16
Cow	0	0	98	0	98
Degu	0	0	25	0	25
Duck	0	0	42	0	42
Ferret	256	0	139	22	161
Gerbil	0	4	45	0	49
Goat	0	0	51	0	51
Gopher	0	0	2	0	2
Hedgehog	0	0	10	0	10
Horse	0	2	317	0	319

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 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	Name & Title of C.E.O. or Institutional Official	Date Signed:
		11/30/2004

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 2150.

See below for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. Registration No: 57-F-0004 / 947

FORM APPROVED
OMB NO. 0579-0036

2. Headquarters Research Facility *(Name and Address, as registered with USDA, include Zip Code)*:

Centers for Disease Control and Prevention
1600 Clifton Road NE
Mailstop C-17
Atlanta, GA 30333
Telephone (404)639-2462

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ***(Attach additional sheets if necessary or use this form.)***

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 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)
Jerboa	0	0	3	0	3
Jird	0	0	40	0	40
Mongoose	0	0	12	12	24
Brush Mouse	0	191	306	0	497
Cactus Mouse	0	2	12	0	14
Deer Mouse	0	2354	3710	0	6064
Dor Mouse	0	0	22	0	22
Northern Grasshopper Mouse	0	23	36	0	59
Pinon Mouse	0	451	1128	0	1579
Plains Pocket Mouse	0	11	9	0	20
Pygmy Mouse	0	0	20	0	20
Rock Mouse	0	0	1	0	1
Silky Pocket Mouse	0	155	0	0	155

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 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	Name & Title of C.E.O. or Institutional Official	Date Signed:
		11/30/2004

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 2150.

See below for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. Registration No: 57-F-0004 / 947

FORM APPROVED
OMB NO. 0579-0036

2. Headquarters Research Facility *(Name and Address, as registered with USDA, include Zip Code)*:

Centers for Disease Control and Prevention
1600 Clifton Road NE
Mailstop C-17
Atlanta, GA 30333
Telephone (404)639-2462

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ***(Attach additional sheets if necessary or use this form.)***

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 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)
Spiney Mouse	0	0	5	0	5
Striped Mouse	0	0	3	0	3
Western Harvest Mouse	0	13	45	0	58
Western Jump9ing Mouse	0	1	0	0	1
White-footed Mouse	0	912	1534	0	2446
Wyoming Pocket Mouse	0	1	0	0	1
Opossum	0	0	6	0	6
Desert Cottontail Rabbit	0	5	0	0	5
Raccoon	0	7	21	9	37
Black Rat	0	0	3	0	3
Cotton Rat	0	0	8	0	8

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 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	Name & Title of C.E.O. or Institutional Official	Date Signed:
		11/30/2004

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 2150.

See below for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. Registration No: 57-F-0004 / 947

FORM APPROVED
OMB NO. 0579-0036

2. Headquarters Research Facility *(Name and Address, as registered with USDA, include Zip Code)*:

Centers for Disease Control and Prevention
1600 Clifton Road NE
Mailstop C-17
Atlanta, GA 30333
Telephone (404)639-2462

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ***(Attach additional sheets if necessary or use this form.)***

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 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)
Gambian Rat	0	0	7	0	7
Kangaroo Rat	0	35	52	0	87
Wood Rat	0	118	394	0	512
Shrew	0	0	57	0	57
Ground Squirrel	0	33	37	0	70
Northern Flying Squirrel	0	4	23	0	27
Rock Squirrel	0	10	1	0	11
Rope Squirrel	0	0	1	0	1
Sun Squirrel	0	0	4	0	4
Sugar Glider	0	0	6	0	6
Vole	0	103	207	0	310
Wallaby	0	10	0	0	10

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 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	Name & Title of C.E.O. or Institutional Official	Date Signed:
		11/30/2004

Tuesday, November 30, 2004

Centers for Disease Control and Prevention
Atlanta, Georgia

Registration Number: 57-F-0004

Facility Locations (Sites)

1. NIOSH, Morgantown, WV 26505

2. DVBD, Foothills Campus, Ft. Collins, CO 80522

3. Clifton Road Research Animal Section
   1600 Clifton Rd NE, Bldg 6 & 15, Atlanta, GA 30333

4. Chamblee Research Animal Section
   4770 Buford Highway, Bldg 15, Chamblee, GA 30341

5. Lawrenceville Research Animal Section
   602 Webb Gin House Rd., Lawrenceville, GA 30045

Tuesday, November 30, 2004

Centers for Disease Control and Prevention
Atlanta, Georgia

Registration Number: 57-F-0004

Column E Explanations for USDA, APHIS form 7023:

HAMSTER

– 138 hamsters, Pain Class III
Agent: Rabies virus
Objective: The Syrian hamster is a recognized animal model useful in the study of rabies post-exposure. Thus, several parameters of Mabs, including efficacy against relevant street strains, with or without vaccine, varying doses, and Mab combinations with different specificities, will be investigated in this animal model.
Explanation of Class III Pain: It is assumed that nearly all the control animals and some of the treated experimental group animals will succumb to rabies. At the first definite sign of rabies, the animals will be euthanized.

– 60 hamsters
Agent: Hemorrhagic fever viruses.
Objective: Assess whether the hemorrhagic fever arenaviruses cause disease that is clinically and pathologically similar to human arenanviral hemorrhagic fevers. Assess the phenotypic significance of the genetic differences among hemorrhagic fever virus species.
Explanation of Class III Pain: The proposed work is a pilot study. It is expected that some of the viral strains will be highly virulent and others will be apathogenic. It is also expected that severe clinical disease in the experimental animals will be peracute. All animals will be monitored closely by experienced personnel. Animals that develop severe illness or that become moribund will be euthanized immediate in order to minimize their suffering.

RABBIT

– 6 rabbits
Agent: Aspergillus, Fusarium, Rhizopus, Mucor spp, opportunistic molds
Objective: Blood, urine, and bronchoalveolar lavage fluid from rabbits infected with species of Aspergillus, Fusaruim, Rhizopus, Mucor, or other opportunistic molds will be used as a source of antigens for the development of tests to diagnose opportunistic filamentous fungal diseases in humans. These fluids, as well as tissue specimens obtained at necropsy, will also be used as targets for the development of DNA probes to diagnose disease. Rabbits will also be used to produce polyclonal antiserum against components from killed fungal cells to be used in diagnostic tests
Explanation of Class III Pain: Infection may cause pulmonary abscesses and abscesses in the liver and spleen. The infection period is short (less than one week) and animals are euthanized before infection is allowed to result in clinical signs other than fever, moist nose, and decreased activity. It is not feasible to administer analgesics since this could interfere with the necessary disease process and lessen production of test antigens by animals. Water and food will be administered ad libidum to reduce stress and anesthetics will be used prior to any inoculations or recovery of blood from the central ear artery.

– 28 rabbits, Pain Class III
Agent: Bacillus anthracis
Objective: Determine efficacy of Anthrax Immune Globulin (AIG) to prevent the development of disease from inhalational anthrax in rabbits. The objective is to test AIG as a future adjunct to therapy for persons ill from inhalational anthrax.
Explanation of Class III Pain: It is assumed that 83 percent of the AIG treated animals will survive and suffer no pain. It is also assumed that all of the non-treated (control) animals will suffer unalleviated pain or distress. Since respiratory failure may be one of the potential causes of death in aerosolized anthrax, analgesics and tranquilizers will not be used to alleviate distress as they also act as respiratory depressants that could potentiate the lethal effects of B. anthracis. All animal observed to be in a state of morbidity will be anesthetized and euthanized.

NON-HUMAN PRIMATE

1174ASHMONX-A2 – 38 rhesus macaque
Agent: Bacillus anthracis
Objective: Conduct a vaccine dosage range study to evaluate the immunological response curves elicited by different concentrations of Anthrax Vaccine, Adsorbed (AVA) in rhesus monkeys. Evaluate various immunological parameters prior to and subsequent to vaccination and challenge that may retrospectively be correlated to appropriate surrogate markers of protection. Overall objective is to produce data to FDA to modify current vaccination regimen and route of injection to reduce number of vaccinations and reactions.

Explanation of Class III Pain: Since respiratory failure may be one of the potential causes of death in aerosolized anthrax, analgesics and tranquilizers will not be used to alleviate distress as they also act as respiratory depressants that could potentiate the lethal effects of B. anthracis. All animal observed to be in a state of morbidity will be anesthetized and euthanized.

– 32 rhesus macaque
Agent: Bacillus anthracis
Objective: Use vaccination of rhesus monkeys with subsequent aerosol anthrax spore challenge to determine the relationship between immune response to Anthrax Vaccine, Adsorbed (AVA) and outcome after challenge. AVA is currently the only vaccine licensed in the USA for protection against human anthrax. This study will be used to determine the probability of protection from anthrax challenge for human AVA vaccines.
Explanation of Class III Pain: It is assumed that 24 percent of the animals suffer pain or distress. Since respiratory failure may be one of the potential causes of death in aerosolized anthrax, analgesics and tranquilizers will not be used to alleviate distress as they also act as respiratory depressants that could potentiate the lethal effects of B. anthracis. All animal observed to be in a state of morbidity will be anesthetized and euthanized.

BAT

– 9 bats
Agent: Rabies virus
Objective: The objective of the initial study is to evaluate the effectiveness of an experimental rabies post-exposure protocol previously applied to the colony of captive bats (E. fuscus) in providing immunity against a known lethal rabies virus challenge.
Explanation of Class III Pain: It is assumed that all the control bats and possibly a few of the vaccinates will succumb to rabies; to minimize suffering, the animals will be sedated and euthanized at the time that compatible rabies signs are observed.

FERRET

– 22 ferrets
Agent: Human, Avian, Swine influenza viruses
Objective: To further study the differences between human, avian and swine viruses, especially on the spread of virus to multiple systemic organs including the brain. Evaluate virulence of newly isolated viruses that have the potential to infect mammals. All work is at BSL 3 containment level.
Explanation of Class III Pain: 1

MONGOOSE

– 12 mongoose

Agent: Rabies virus

Objective: Our objectives are to determine the basic safety, immunogenicity, potency, and efficacy of commercial and experimental rabies vaccines per os or in vaccine-laden baits.

Explanation of Class III Pain: It is assumed that nearly all the control animals and some of the treated experimental group animals will succumb to rabies. Animals will be euthanized at the first definite sign of rabies.

RACCOON

– 9 raccoons

Agent: Rabies virus

Objective: The objective of the initial study is to evaluate the effectiveness of an experimental oral vaccine in providing immunity to a known lethal rabies street virus of raccoon origin.

Explanation of Class III Pain: It is assumed that nearly all the control animals and some of the treated experimental group animals will succumb to rabies. At the first definite sign of rabies, the animals will be euthanized.

Tuesday, November 30, 2004

Centers for Disease Control and Prevention
Atlanta, Georgia

Registration Number: 57-F-0004

Exceptions to Regulations and Standards:

During the reporting period, the following variance to the Animal Welfare Act was granted by the CDC – Atlanta Institutional Animal Care and Use Committee:

1. Regarding cage size for a Chimpanzee – An issue brought forth for IACUC consideration is that there are several chimpanzees that are larger than 50 kilograms and need a larger volume of space than the current enclosures allow (not in compliance with the AWA requirements of 25.1 sq ft. for apes over 25 kg). The Animal Resources Branch is implementing a policy that 50 kilograms is the largest a chimpanzee can be before they are transferred to another facility. Dr. Gale Galland is requesting a variance for one year for two chimpanzees at 48kg and 55kg as they are getting ready to be put on a study. One is currently under the limit, but will be past the threshold during the course of the study. The committee voted as a quorum (6 in favor, 0 opposed, 1 abstain) to approved the variance at the March 10, 2004 IACUC meeting. The animals will be relocated after one year.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FORM APPROVED
-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
57-F-0004

2. HEADQUARTERS ADDRESS (Include Zip Code)
57-F-0004, Cust Id 947
~~DR BOBBY G BROWN~~ Dr. Gale Galland
CTR. FOR DISEASE CNTL. & PREV.
1600 CLIFTON ROAD, NE MS:G28
ATLANTA, GA 30333

USDA

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)*

VBD, Foothills Campus, Ft. Collins, CO 80522
IOSH, Morgantown, WV 26505
Clifton Road Research Animal Section
600 Clifton Rd NE, Bg 6/15, Atlanta, GA 30333
Chamblee Research Animal Section
4770 Buford Hwy, Blg 15, Chamblee, GA 30341
Lawrenceville Research Animal Section
602 Webb Gin House Road, Lawrenceville, GA 30045

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	0	39	30	16	85
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	607	62	669
7. Hamsters	14	0	513	188	701
8. Rabbits	45	24	117	13	154
9. Non-human Primates	0	227	329	44	600
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Goats	0	1	1	0	2
13. Other Animals					
Chimpanzees	0	0	24	0	24
Cows	0	0	6	0	6

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
		11/30/2000

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART I - HEADQUARTERS

57-F-0004

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA include Zip Code)*

Dr. Gale Galland
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS: G28
Atlanta, GA 30333

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

Animals Covered By The Animal Welfare Regulations — 12 &/OR 13 Other (List by species)	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)
Ferrets	33	0	161	16	177
Gerbils	8	0	18	0	18
Horses	0	2	0	0	2
Mice, White Footed	20	0	0	0	0
Raccoons	0	0	12	12	24
Skunks	0	0	6	4	10
				32	

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
		11/30/2000

APHIS FORM 7023A
(AUG 91)

PART I HEADQUARTERS

November 28, 2000

Centers for Disease Control and Prevention
Atlanta, Georgia - Registration Number 57-F-0004

Column E explanations for USDA, APHIS form 7023:

The research protocols on 10 of the nonhuman primates (#909), 16 dogs (#896), 16 ferrets (#1010), 4 skunks (#968), 12 raccoons (#970), and 188 hamsters (#912) reported in column E were all part of ongoing rabies studies. Anesthetics and/or analgesics were used for routine veterinary procedures as needed. The animals were challenged with a live rabies virus to determine the efficacy of the vaccine or the virulence of the virus. Those which developed clinical signs of rabies were euthanized to prevent progression of disease past the point of confirmed diagnosis. Most animals were actually in pain category D, but because a few animals died acutely from the disease they were placed in category E.

Eight nonhuman primates (#974, #1112) were utilized in Ebola pathogenesis and DNA vaccine efficacy studies. Forty-six guinea pigs (#1064,#1114) were utilized to study the pathogenesis of Lyssavirus and Nipah virus. Eight nonhuman primates (#1129) were used in variola virus research to study pathogenicity and assess drug and vaccine efficacy. Due to the nature of these agents and disease progression, these animals were placed in category E. As disease progressed and animals became moribund, they are euthanized. Additionally, six rabbits (#1109) were used in variola virus research for which antibodies were developed using Freund's adjuvant.

Eighteen nonhuman primates (#1056, #1059) were used in malaria studies for which the immunogenicity and efficacy of potential vaccines were tested using Freund's adjuvant.

Six rabbits (#1091) were used in fungal studies to produce antigens for PCR/ELISA-based diagnostic tests. Due to the short infection period (one week or less), animals demonstrating clinical signs were euthanized to prevent disease progression. One rabbit (#1089) was used in schistomsomiasis research for which anti-idiotypic antibodies were developed using Freund's adjuvant.

Sixteen guinea pigs (#1126) were utilized to study the pathogenesis of Mycobacterium ulcerans. Though these animals were treated with appropriate analgesics as needed, they were placed in category E due the nature of the agent and disease progression.

During the reporting period, one variance was granted by the Atlanta Animal Care and Use Committee regarding cage size. Female rabbits weighing about 2 kilograms were ordered for a variola antibody production study which was performed in the Biosafety Level (BSL) IV facility. The study was to last approximately 2 months and the concern of the investigator was that the animals could potentially reach the 4 kilogram weight limit for the 3.0 cage size in the BSL IV. The variance was granted to allow the animals to remain in these cages until the expected end of the study even if they exceeded the weight limit.

can

additional information

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 57-F-0004
CUSTOMER NUMBER: 947

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Centers for Disease Control and Prevention
1600 Clifton Road N.E.
Mailstop C-17
Atlanta, GA 30333

NOV 26 2002

Telephone: (404) 639-2462

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	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, a	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	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	4	0	4
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	42	886	28	956
7. Hamsters	41	0	361	156	517
8. Rabbits	28	86	246	0	332
9. Non-human Primate	104	60	995	63	1118
10. Sheep	0	0	0	0	0
11. Pigs	0	0	16	0	16
12. Other Farm Animals					
13. Other Animals					
;at	43	14	3	0	17
:ow	0	0	5	0	5
'erret	65	0	203	12	215

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, 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

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

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

3], which is obsolete.

12/2/02

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150 additional information. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO.
Certificate # 57-F-0004

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Centers for Disease Control and Prevention
1600 Clifton Road N.E.
Mailstop C-17
Atlanta, Ga 30333 Telephone: (404) 639-2462

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12 &/OR 13. Other *(List by species)*	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)
Fields Study (Wild Rodents & Birds)	0	0	163	0	163
Gerbil	16	0	9	0	9
Goat	0	1	3	0	4
Horse	0	0	2	0	2
Mongoose	33	0	11	0	11
Deer Mouse	0	0	543	0	543
Grasshopper Mouse	0	0	4	0	4
HSD NIHS Mouse	0	0	1474	0	1474
Pine Mouse	0	0	40	0	40
CFW Mouse	0	0	203	0	203
Various Mice	0	600	1200	0	1800
Prairie Dog	0	0	18	0	18
Blacktail Rabbit	0	0	1	0	1
Raccoon	0	0	8	16	24
Cotton Rat	0	0	56	0	56
Mexican Woodrat	0	0	52	0	52
Skunk	0	0	5	0	5

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 HEADQUARTES 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

A

PART 1 - HEADQUARTERS

Thursday, November 21, 2002

Centers for Disease Control and Prevention
Atlanta, Georgia

Registration Number: 57-F-0004

Column E Explanations for USDA, APHIS form 7023:

– 8 ferrets, Pain Class III –
Agent: Avian H9N2 viruses and pathogenic H5N1 virus
Objective: Establish a model system to be used to evaluate potential vaccine strategies for pandemic influenza.
Explanation of Class III Pain: Infection of ferrets with highly pathogenic H5N1 viruses may cause severe morbidity, including neurological symptoms and occasionally, death. Animals are monitored daily and will be euthanized should neurological symptoms be observed.

– 4 ferrets, Pain Class III –
Agent: Human wild-type H3N2 virus and H5N1 virus
Objective: Develop ferret model to study the molecular basis of influenza virus transmission at BSL 3+ containment.
Explanation of Class III Pain: Infection of ferrets with highly pathogenic H5N1 viruses may cause severe morbidity, including neurological symptoms and occasionally, death. Animals are monitored daily and will be euthanized should neurological symptoms be observed.

– 28 guinea pigs, Pain Class III –
Agent: Various filoviruses (4 species of Ebola virus and 1 strain of Marburg virus)
Objective: To assess the protection induced in guinea pigs to the structural glycoprotein of Ebola virus (Zaire species), which contains insertions of various combination of filovirus mucin-like regions. Identify potentially important immunogens that will lead to a protective vaccine effective against all forms of filovirus disease.
Explanation of Class III Pain: Unprotected animals (control) will likely die of a severe filovirus infection, but protected animals should show little or no disease. Since this is a vaccine study, animals cannot be given drugs to relieve pain or distress without compromising results.

– 156 hamsters, Pain Class III –
Agent: Rabies virus
Objective: Investigate several post-exposure parameters of Mabs (Monoclonal antibodies), including efficacy against relevant street strains, with or without vaccine varying doses, and Mab combinations with different specificities.
Explanation of Class III Pain: It is assumed that nearly all the control animals and some of the treated experimental group animals will succumb to rabies. Animals will be euthanized at the first definite sign of rabies.

– 24 Non-human primates, Pain Class III –

Agent: *Plasmodium falciparum* FVO and Malayan Camp strains

Objective: Immunization trial (using two forms of rMS-1p42 and three adjuvants) testing for 1) efficacy and immunogenicity, 2) induction of protective immunity, 3) parallel vaccinations, and 4) comparability of data between immunization trials in *Aotus nancymai* and clinical trial immunization in humans using the same adjuvants, schedules, and clinical grade cGMP antigens.

Explanation of Class III Pain: Use of Complete Freund's Adjuvant

– 6 Non-human primates, Pain Class III –

Agent: *Plasmodium falciparum* Vietnam Oak Knoll, Uganda pal Alto & Indochine I strains

Objective: Validate *S. B. boliviensis* as an immunizations trial model equal to *A. nancymai*. Evaluate the immunogenicity and efficacy of milk derived rMSP-1p42 in comparison to the known efficacy of this rMSP-1p42 in *Aotus nancymai* when adjuvanted with RCA in protecting against high density parasitemia from the FVO strain of P. falicparum.

Explanation of Class III Pain: Use of Freund's Adjuvant

– 32 Non-human primates, Pain Class III –

Agent: Rabies Virus

Objective: Evaluate the Immunogenicity, safety, and efficacy of different rabies vaccines, and purified, heat-treated ERIG, and varius Mabs (murine, chimeric, human, and recombinant) in conjunction with rabies vaccine, as a potential replacement for HRIG, in squirrel monkeys during vaccination against several variants of lethal street rabies virus.

Explanation of Class III Pain: It is assumed that nearly all the control animals and possibly a few of the vaccinates will succumb to rabies. Animals will be euthanized when two compatible signs of rabies are observed.

– 1 Non-human primate, Pain Class III –

Agent: *Baylisascaris procyonis*

Objective: To generate large quantities of diagnostic assay reagents (sera and infected tissues) to study the pathological effects of infection, and describe the pattern of disease.

Explanation of Class III Pain: *Baylisascaris procyonis* cause visceral larva migrans and cerebrospinal parasitosis in infected humans. The severity and progression of CNS disease depends on the number of *B. procyonis* larvae entering the brain. An estimated 5-7% of larvae will invade the brain. In humans, recognized *B. procyonis* infection has typically caused fatal disease or severe sequellae. Signs of CNS disease may appear as early as 2-4 weeks post infection. Typical signs in human infections include sudden lethargy, loss of muscle coordination, decreased head control, torticollis, ataxia, and nystagmus, progressing to stupor, extensor rigidity or hypotonia, coma and death.

– 16 Raccoons, Pain Class III –

Agent: Rabies virus

Objective: To evaluate the effectiveness of SAF2 in a bait, as well as the comparative efficacy of various experimental oral vaccines in raccoons in providing protection against a challenge with lethal street rabies virus of raccoon origin.

Explanation of Class III Pain: It is assumed that nearly all the control animals and possibly a few of the vaccinates will succumb to rabies. To minimize suffering, the animals will be euthanized at the time that definite rabies signs are observed.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 57-F-0004 CUSTOMER NO. 947

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

CTR. FOR DISEASE CNTL. & PREV.
1600 CLIFTON ROAD, NE MSG-28
ATLANTA, GA 30333
(404) 639-1320

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)*

~~See Attached Listing~~ NIOSH, Morgantown, WV 26505

DVBD, Foothills Campus, Ft. Collins, CO 80522

Chamblee Research Animal Section
4770 Buford Hwy, Bg. 15, Chamblee, GA 30341

Clifton Road Research Animal Section
1600 Clifton Rd NE, Bg 6/15, Atlanta,GA 30333

Lawrenceville Research Animal Section
602 Webb Gin House Rd, Lawrenceville, GA 30045

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	0	28	0	0	28
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	758	15	773
7. Hamsters	13	0	165	0	165
8. Rabbits	9	46	178	47	271
9. Non-Human Primates	37	4	704	55	763
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Cows	0	0	4	0	4
13. Other Animals					
Baboons	2	0	0	0	0
Chimpanzees	0	0	21	0	21
Ferrets	66	82	221	42	345

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 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)

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

DATE SIGNED 11/29/01

FORM 7023 G 91) (Replac FORM 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 57-F-0004 CUSTOMER NO. 947

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

CTR. FOR DISEASE CNTL. & PREV.
1600 CLIFTON ROAD, NE MSG-28
ATLANTA, GA 30333
(404) 639-1320

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Gerbils	15	0	5	0	5
Goats	0	0	2	0	2
Horse	0	2	0	0	2
Mongoose	0	1	11	4	16
Mouse,White Footed	0	24	132	0	156
Mouse, Meadow	0	0	20	0	20
Mouse, pine	7	0	28	10	38
Raccoon	0	12	8	0	20
Rat, Cotton	14	24	64	8	96
Skunk	12	0	0	0	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, 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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/29/01

M 7023A (Repla S FORM 18), which is obsolete

PART 1 - HEADQUARTERS

November 20, 2001

Centers for Disease Control and Prevention
Atlanta, Georgia - Registration number 57-F-0004

Column E explanations for USDA, APHIS form 7023:

The research protocols on two of the ferrets (#1010) and four of the mongoose (#1140) reported in column E were all part of ongoing rabies studies. Anesthetics and/or analgesics were used for routine veterinary procedures as needed. The animals were challenged with a live rabies virus to determine the efficacy of the vaccine, the virulence of the virus, or the pathophysiology of the disease in that species. Those which developed clinical signs of rabies were euthanized to prevent progression of disease past the point of confirmed diagnosis. Most animals were actually in pain category D, but because a few animals died acutely from the disease they were placed in category E.

The 40 ferrets reported on protocol #1077 were used in studies involving H5N1 influenza viruses. Infection of humans with H5N1 viruses resulted in a 33% mortality rate. If the ferret is to be a useful model for infection with these viruses, it is important to determine if it reacts similarly when infected. Based on serological studies, where some unexpected deaths were observed in H5N1 virus infected ferrets, we expect that 10 - 30% of animals may develop severe disease and/or death from infection of highly pathogenic avian H5 viruses. Any animals that were found in a moribund state (near death and are not expected to recover), were euthanized.

Six of the primates on protocol # 1186 were used in malaria studies for which the immunogenicity and efficacy of potential vaccines were tested using Freund's adjuvant.

One rabbit on protocol #1089 was used to obtain hyperimmune serum to schistosomiasis using Freund's adjuvant. The serum produced will be compared to other hyperimmune serum produced with other adjuvants.

Forty-six rabbits were used on protocol #1190 for the production of hyperimmune serum against smallpox. Four of these rabbits received Freund's adjuvant. The remainder were inoculated with smallpox vaccine viruses to produce the immune serum. Because of the nature of the pox lesions and the Freund's lesions, all of these animals were placed in category E. Analgesics were administered as necessary.

Twenty nonhuman primates (#1188) and six nonhuman primates (#1195) were used for safety studies of new smallpox vaccines being developed. Anesthetics and analgesics were used as necessary. None of the animals were reported with problems secondary to the studies but because these studies were being conducted at contract facilities and because there was a potential for encephalitis secondary to the studies, we placed all animals in category E.

Twenty-three nonhuman primates were used in studies of pathogenicity of the smallpox virus. Appropriate anesthetics and analgesic were used for procedures during the study. When animals met the criteria for "terminally ill" (such as: progressive state of depression, recumbency, inappropriate responses to external stimuli, forced abdominal respiration and dyspnia) they were humanely euthanized.

Eight cotton rats (#1167) and 10 pine mice (#1169) were used in pathogenic studies of Rickettsia rickettsii. Most of the animals in these studies did not show clinical illness and were reported in pain category D. However, since these animals did exhibit signs of serious disease, they were reported in category E.

Fifteen guinea pigs (#1126) were utilized to study the pathogenesis of Mycobacterium ulcerans. Though these animals were treated with appropriate analgesics as needed, they were placed in category E due to the nature of the agent and disease progression.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

12-10-2001 RCVD

1. REGISTRATION NO. 57-F-0005 CUSTOMER NO. 946

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

ARS-USDA RB RUSSELL AG.RES.CTR
P.O. BOX 5677, 950 COLLEGE STA
ATHENS, GA 30613
(999) 999-9999

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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			39		39
12. Other Farm Animals			3779		3779
13. Other Animals					
RATS		54	35		89
MICE		20	32		52

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 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 IN ITIONAL C IAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
GENE LYON		12/4/01

PART 1 - HEADQUARTERS

APHIS FORM 7023 (AUG 91) (Replaces VS M 18-23 (Oct 88), which is obsolete

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 71-F-0002 CUSTOMER NO. 1431

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

FDA/NCTR
OFFICE OF RESEARCH SERVICES
3900 NCTR DR
JEFFERSON, AR 72079
(870) ~~(501)~~ 543-7949

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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		16			16
9. Non-Human Primates	22	56			~~78~~ 72
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.

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.

OCT 26 2001

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
		10-22-01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 72-F-0004 CUSTOMER NO. 1385

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NAT'L HANSEN'S DISEASE
1770 PHYSICIANS PARK DR
BATON ROUGE, LA 70816

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)*

GWLHDC
CARVILLE, LA 70894

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					
Armadillos	50	200			200
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/09/2001

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

APHIS Form 7023 Additional Reported Sites

The following additional sites have been reported by the facility. The reported sites have not been verified by APHIS and have been provided by the facility solely for completeness of the APHIS Form 7023 Annual Reporting submission.

Registration Number: 72-F-0004
Customer Number: 1385
Facility: NAT'L HANSEN'S DISEASE
1770 PHYSICIANS PARK DR
BATON ROUGE, LA 70816

This is the only site housing animals:
Laboratory Research Branch
National Hansen's Disease Programs @ LSU-SVM
Skip Bertman Drive
Baton Rouge, LA 70803
Tel: 225-578-9861

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 81-F-0002 CUSTOMER NO. 1293

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

USDA, ARS
ROUTE 1, BOX 2021
MILES CITY, MT 59663

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)*

FORT KEOGH LIVESTOCK
MILES CITY, MT 59663

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					
Cattle		2368	37		2405
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		12/03/2001

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 82-F-0002 **CUSTOMER NO.** 1203

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

USDA, AGRIC. RES. SERV.
HC 62, BOX 2010
DUBOIS, ID 83423

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)*

U. S. SHEEP EXPERIMENT STATION
DUBOIS, ID 83423

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	2515	3215	82	38	3335
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		09/30/2003

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 82-F-0002

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

Sheep (38)

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

Restraint stress was used to determine whether rams with different libido classifications responded differently to adrenal-cortical activation. Restraint stress, compared with minimal stress, was imposed on high libido, low libido, and asexual rams in a 2 x 3 factorial experiment: stress and ram classification were main effects. To induce restraint stress, rams were haltered in separate pens and laid on their side with legs tied for 1 h. The front and hind legs were tied separately with only enough rope tension to prevent the rams from injuring themselves when they struggled. For minimal stress (as opposed to restraint stress), rams were haltered, tethered, and left in their home pens. Jugular blood was collected at various time point and was subsequently analyzed cortisol and testosterone.

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)

Due to the objective of the trial, "determine the effect of stress on corticoids and testosterone in mature rams with no libido, low libido and high libido", some degree of stress was required in order to induce a potential alteration in stress and reproductive hormone profiles. Following the stressor periods, rams were immediately returned to a non-stress environment (e.g., free movement, social interaction). No attempts were made to relieve targeted and preplanned stressor treatments; this would only negate the treatment effect being tested. However, immediate relief from non-planned stressors (e.g., thrashing about) was administered when required.

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: CFR:

1. Registration Number: 82-F-0002 / 1203

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

Sheep (38)

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

Restraint stress was used to determine whether rams with different libido classifications responded differently to adrenal-cortical activation. Restraint stress, compared with minimal stress, was imposed on high libido, low libido, and asexual rams in a 2 x 3 factorial experiment: stress and ram classification were main effects. To induce restraint stress, rams were haltered in separate pens and laid on their side with legs tied for 1 h. The front and hind legs were tied separately with only enough rope tension to prevent the rams from injuring themselves when they struggled. For minimal stress (as opposed to restraint stress), rams were haltered, tethered, and left in their home pens. Jugular blood was collected at various time point and was subsequently analyzed cortisol and testosterone.

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)

Due to the objective of the trial, "determine the effect of stress on corticoids and testosterone in mature rams with no libido, low libido and high libido", some degree of stress was required in order to induce a potential alteration in stress and reproductive hormone profiles. Following the stressor periods, rams were immediately returned to a non-stress environment (e.g., free movement, social interaction). No attempts were made to relieve targeted and preplanned stressor treatments; this would only negate the treatment effect being tested. However, immediate relief from non-planned stressors (e.g., thrashing about) was administered when required.

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: CFR:

Approval Status:
Approved/Disapproved By:
Date:

Disapproved Reason:

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 2150 Cust # 1209

See reverse side for additional information

Interagency Report Control No. 011

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 84-F-0001

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)

USDA, APHIS, WS, NWRC
4101 LAPORTE AVE.
FT. COLLINS, CO 80521

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.)

COPY FOR YOUR INFORMATION

FACILITY LOCATIONS (Sites)	

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 those 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	24	34	0	0	34
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Goats	21	23	0	0	23
13 Other Animals					
Coyotes	28	77	16	35	128
Norway Rats	0	7	0	0	7
Deer Mice	18	24	0	0	24

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 CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/28/04

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88) which is obsolete

NOV - 4 20

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 2150

Set reverse side for additional information

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 84-F-0001

FORM APPROVED
OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)

USDA, APHIS, WS, NWRC
4101 LAPORTE AVE.
FT. COLLINS, CO 80521

COPY FOR YOUR INFORMATION

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 — 12. &/OR 13. Other (List by species)	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 those animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
Ground Squirrels	0	30	0	0	30
Fox Squirrels	0	13	0	0	13
Skunks	0	33	0	0	33
Raccoons	0	67	0	0	67
Mountain Beaver	19	32	0	5	37
Stream Beaver	19	22	0	0	22
White Tail Deer	13	15	0	0	15
Black Tail Deer	90	57	0	0	57
Voles	60	0	0	0	0
Porcupine	3	0	0	0	0
Pocket Gophers	5	0	0	0	0
Mongoose	0	6	0	0	6

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 CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/28/04

APHIS FORM 7023A
(AUG 91)

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 predacides. 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 methyxanthine 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

Column E explanation for QA 1118

Registration Number: 84-F-0001
Number of animals used: 5
Species (common name): Mountain Beaver

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 [redacted] 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 [redacted] 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 (John A. Macan, Standard rat anticoagulant place pack dry bait laboratory methods, Guideline #1.217).

October 25, 2004

NWRC, FY 2004
Aphis Form 7023, attch #1

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

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 84-F-0001 CUSTOMER NO. 1209

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

USDA, APHIS, WS, NWRC
4101 LA PORTE AVENUE
FORT COLLINS, CO 80521
(970) 266-6000

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)*

See Attached Listing X

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			32		32
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
NORWAY RATS			70		70
COYOTES	23	84	48		132
POCKET GOPHERS		8		88	96

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/02/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 84-F-0001 | CUSTOMER NO. 1209

FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

USDA, APHIS, WS, NWRC
4101 LA PORTE AVENUE
FORT COLLINS, CO 80521
(970) 266-6000

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
HOUSE MICE	9				
VOLES	97				
FIELD MICE	64				
BLACK-TAILED DEER	29	34			34
WHITE-TAILED DEER	14	3			3
MOUNTAIN BEAVER	36	9			9
PORCUPINE	2				
WEASEL	7				7
	270	46	48	60 30	

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/02/01

APHIS FORM 7023A (AUG 91)

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

PART 1 - HEADQUARTERS

Subject: Explanation for Animals Listed in Column E.

Registration No. 84-F-0001

Pocket Gophers (88)

This study permitted observations and measures of activities (predation, secondary poisoning) that occur naturally or which may occur post an operational baiting program. Weasels naturally prey on pocket gophers and may be subject to secondary hazards posed by strychnine baiting implemented to reduce pocket gopher populations. The only possible means to determine whether strychnine poisoned pocket gophers pose a secondary hazard to weasels is to observe weasel interactions with strychnine poisoned pocket gophers. Specifically, whether weasels will kill and subsequently ingest pocket gophers that are behaviorally and physiologically impaired due to strychnine toxicosis.

Three test regimes were used during the study: 1) weasel response when they encounter non strychnine poisoned pocket gophers; 2) weasel response when they encounter gophers that have been poisoned with strychnine; and 3) weasel response to 5 and 10 day old carcasses of pocket gophers that died from strychnine poisoning. Pocket gophers died from strychnine treatments. Interactions between predators and prey species were likely to induce pain and were fatal to the prey.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 84-F-0009 CUSTOMER NO. 1214

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

DEPT. OF AIRFORCE
DEPT. OF BIOLOGY
AIR FORCE ACADEMY, CO 80840-5000

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)*

U. S. AIRFORCE ACADEMY
AIR FORCE ACADEMY, CO 80840-5000

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					
chickens		12			12
13. Other Animals					
meadow voles		41			41

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/29/2001

1-17-02

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 87-F-0001 CUSTOMER NO. 1210

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

USDA-ARS-POISIONOUS PLANT RESEARCH LAB
1150 EAST 1400 NORTH
LOGAN, UT 84321
(801) 752-2941

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)*

See Attached Listing

USDA ARS PPRL
1150 EAST 1400 NORTH
LOGAN UT 84341

USDA ARS PPRL
8462 N. HWY 91
RICHMOND UT 84333

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		2			2
6. Guinea Pigs					
7. Hamsters		90			90
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals (Deer)		10			10

RECEIVED
OCT - 1 2001

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		9/26/01

A FORM 7023 (IG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150 [illegible] confidential information [illegible]

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 88-F-0001 | Laris FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, Include Zip Code)* 1197

USDA, Agricultural Research Service
920 Valley Road
Reno, NV 89512
Telephone: 775-784-6057

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)*

920 Valley Rd.; Reno, NV 89512

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Kangaroo rats	0	78	0	0	78
Kangaroo mice	0	17	0	0	17
Pocket mice	0	27	0	0	27

ASSURANCE STATEMENTS 127

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
		11/27/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

RECEIVED
NOV 29 2001
USDA, APHIS, REAC, AC
SACRAMENTO, CA

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 91-F-0001 | CUSTOMER NO. 1207

FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL MARINE MAMMALS LABS.
7600 SAND PT WAY, NOAA BLDG. 32
SEATTLE, WA 98115
(206) 526-4048

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
California Sea Lion		62		566 hot branded	628
Steller Sea Lion - ~~PB~~ Oregon			180 hot branded	~~150 hot branded~~	180
Pacific harbor seal				50 hot branded	50
Beluga whale		7			7
		69	462	616	

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		14-11-01

APHIS FORM 7023A
(AUG 91)

3-23 (Oct 88), which is ol

PART 1 - HEADQUARTERS

FACILITY LOCATIONS

The reported animals were captured and restrained for various tagging or instrumentation studies and health monitoring studies in various remote field locations including: eastern Aleutian Islands, Alaska; western Gulf of Alaska, San Miguel Island, California; Puget Sound, Washington; Cook Inlet, Alaska; Rogue Reef, Oregon

COLUMN "D" & "E" EXPLANATION

Registration Number: 91-F0001
Customer Number 1207

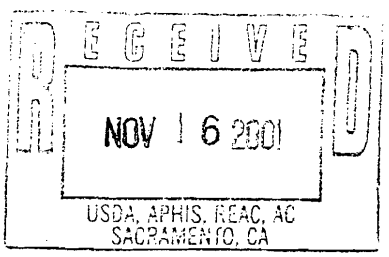
During the reporting period, the National Marine Mammal Laboratory used hot branding to make individual markings on 566 California sea lions, 50 harbor seals and 462 Steller sea lions. This procedure is accompanied by minor pain and distress which is in some cases addressed with drugs.

Using current methodology, the hot branding procedure takes 1 to 2 minutes. The time and condition of restraint for weighing, measuring, tagging and sampling are as follows:

Steller sea lions are restrained with gas anesthesia, with holding time of up to 15 minutes for animals which are blood sampled as part of health screening (approximately 20 % of animals handled) and for the remaining 80% of animals handling times are about 5 minutes with branding taking about 1 minute.

California sea lion pups are handled with physical restraint, holding time is about 5 minutes for each animal, with branding requiring about 1 minute. California sea lion adult males are held with physical restraint using a squeeze cage for sampling and branding. Holding time is approximately 10 minutes per animal, with branding taking about 1 minute.

Harbor seals are physical restrained with handling times of about 5 minutes for each animal, and branding takes an average of 1 minute.



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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 91-F-0001 CUSTOMER NO. 1207

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NATIONAL MARINE MAMMALS LABS.
7600 SAND PT WAY, NOAA BLDG. 32
SEATTLE, WA 98115
(206) 526-4048

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)*

See Attached Listing
See attached

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					
Alaskan Harbor Seals		52			52
Steller Sea lions		154	282-hotbrnd	~~252 - hot brnd~~	436
Northern fur seal		1,102			1,102

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		14-11-01

APHIS FORM 7023
(AUG 91)

obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 91-F-0002 CUSTOMER NO. 1212

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

DEPT. OF CLINICAL INVESTIGATIONS
COMMANDER, MADIGAN ARMY MEDICAL CTR.
DEPARTMENT OF CLINICAL INVESTIGATION
TACOMA, WA 98431

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)*

DEPT. OF CLINICAL INVESTIGATIONS
TACOMA, WA 98431

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			5		5
9. Non-Human Primates					
10. Sheep					
11. Pigs			6		6
12. Other Farm Animals					
Goat			25		25
13. Other Animals					
Ferret			9		9
Rat			42		42
Mouse			31		31

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/21/2001

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150. additional information. 0180-DOA-AN 12/20/01

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 91-F-0007 CUSTOMER NO. 1213

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

USDA/ARS/ANIMAL DISEASE RESEARCH UNIT
337 BUSTAD HALL
WASHINGTON STATE UNIVERSITY
PULLMAN, WA 99164
(509) 335-6029

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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			11		11
9. Non-Human Primates					
10. Sheep	3	241			241
11. Pigs					
12. Other Farm Animals					
Goats		20			20
13. Other Animals					
Cattle	27		53		53
Horses	18		3		3

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 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.

RECEIVED NOV 27 2001 USDA, APHIS, REAC, ACI

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
		11/26/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	91-F-0007
Customer Number:	1213
Facility:	USDA/ARS/ANIMAL DISEASE RESEARCH UNIT 337 BUSTAD HALL WASHINGTON STATE UNIVERSITY PULLMAN, WA 99164 (509) 335-6029

USDA/ARS/ANIMAL DISEASE RESEARCH UNIT
337 BUSTAD HALL
WASHINGTON STATE UNIVERSITY
PULLMAN, WA 99164

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 2150.

See reverse side for additional information.

Laris Interagency Report Control No. 0180-DOA-AN 1/1860

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 92-F-0004 | CUSTOMER NO. 1262 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

USDA - FORESTRY AND RANGE SCIENCES LAB
1401 GEKELER LANE
LA GRANDE, OR 97850
(541) 963-7122

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)*

See Attached Listing
Starkey Experimental Forest and Range

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					
Wild Mule Deer	0	68	0	0	68
Wild Elk	0	566	0	0	566
Tame Elk	48	14	0	0	62

ASSURANCE STATEMENTS 646

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 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.

DEC 12 2001
USDA, APHIS, REAC, AC
SACRAMENTO, CA

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
		1 Dec 2001

I 18-23 (Oct 88), which is obsolete

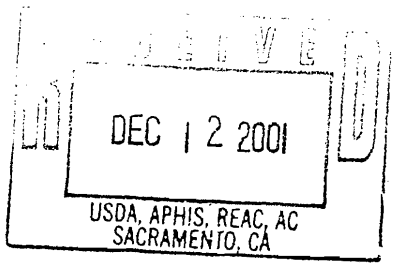
PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 92-F-0004
Customer Number: 1262
Facility: USDA - FORESTRY AND RANGE SCIENCES LAB
1401 GEKELER LANE
LA GRANDE, OR 97850
(541) 963-7122

STARKEY DEER & ELK RES. & DEV.
1401 GEKELER LANE
LA GRANDE, OR 97850



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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

Laris

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 93-F-0001 CUSTOMER NO. 1198

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

LAWRENCE BERKELEY NATIONAL LABORATORY
1 CYCLOTRON ROAD, BLDG. 74
BERKELEY, CA 94720
(510) 486-5221

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)*

~~See Attached Listing~~

Lawrence Berkeley National Lab, Bldg 74

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	0	1	8		9
5. Cats	0				
6. Guinea Pigs	0				
7. Hamsters	0				
8. Rabbits	0	9	31		40
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, 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 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)

SIGN.	L OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
			11/16/2021

APHIS FORM 7023 (AUG 91)

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

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Laris Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-F-0005 CUSTOMER NO. 1199

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

SPAWARSYSCEN
D35 BIOSCIENCES DIVISION
53560 HULL STREET (619) 553-5252
SAN DIEGO CA 92152

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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		Distribution limited to U.S. Government agencies only.			
5. Cats		Administrative/operational use, 6 Nov 01. Other requests for this document shall be referred to the Commanding Officer, Space and Naval			
6. Guinea Pigs		Warfare Systems Center, San Diego, CA 92152-5001. Professionally acceptable standards governing the care, treatment and use			
7. Hamsters		of animals, including appropriate use of anesthetic, analgesic and tranquilizing drugs are a primary component of the veterinary care program.			
8. Rabbits		The Institutional Animal Care and Utilization Committee reviewed all research protocols and found them to be in compliance with all			
9. Non-Human Primates		animal welfare regulations.			
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
White Whales	1	1	0	0	1
Dolphins	0	30	0	0	30
Sea Lions	0	2	0	0	2

RECEIVED
NOV 16 2001
USDA, APHIS, REAC, AC

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 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)

SIGN STITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/4/01

S FORM 7023 (Replaces VS FORM 18-23 (Oct 88), which is obsolete PART 1 - HEADQUARTERS
UG 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 2150.

See reverse side for additional information.

Laris Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-F-0006 CUSTOMER NO. 1200

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NASA
ANIMAL CARE FACILITY
MAIL STOP 261-1
MOFFETT FIELD, CA 94035
(415) 604-5000

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	25		171		171
9. Non-Human Primates	8	3	1		4
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
chinchillas	12		15		15

RECEIVED
OCT 10 2001
SACRAMENTO, CA

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10-15-01

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

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 93-F-0006
Customer Number: 1200
Facility: NASA
ANIMAL CARE FACILITY
MAIL STOP 261-1
MOFFETT FIELD, CA 94035
(415) 604-5000

AMES RESEARCH FACILITY
ANIMAL CARE FACILITY
MOFFETT FIELD, CA 94035

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

Laris

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 93-F-0008 CUSTOMER NO. 1202

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

NAVAL MEDICAL CTR SAN DIEGO
STE 5, DIV. OF ANIMAL RESOURCES
34800 BOB WILSON DRIVE
SAN DIEGO, CA 92134
(619) 532-6944

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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			10		10
6. Guinea Pigs	6		147		147
7. Hamsters					
8. Rabbits	7	24	35		59
9. Non-Human Primates					
10. Sheep					
11. Pigs	10		154		154
12. Other Farm Animals					
13. Other Animals					
Chinchilla	25		39	63	102

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.

NOV 23

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	NAME & TITLE OF C.E.O. O	DATE SIGNED
		11/14/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

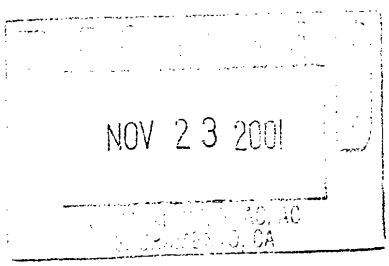
PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	93-F-0008
Customer Number:	1202
Facility:	NAVAL MEDICAL CTR SAN DIEGO STE 5, DIV. OF ANIMAL RESOURCES 34800 BOB WILSON DRIVE SAN DIEGO, CA 92134 (619) 532-6944

DIVISION OF ANIMAL RESOURCE
34800 BOB WILSON DRIVE
SAN DIEGO, CA 92134



Column E Explanation

Registration Number: Certificate Number 93-F-008, Customer Number 1202

Number and Species of Animals: 63 Chinchillas

Explanation of Procedure Causing Possible Distress: Individual housing in an unfamiliar environment and exposure of chinchillas to 4kHz octave band noise at 105 dB sound pressure level for a duration of 6 hours. This procedure is considered non-painful but may induce distress. This exposure induces cochlear hair cell loss and a significant hearing threshold shift. This model is utilized to test various means to protect against cochlear hair cell loss and to potentially reverse cochlear hair cell loss.

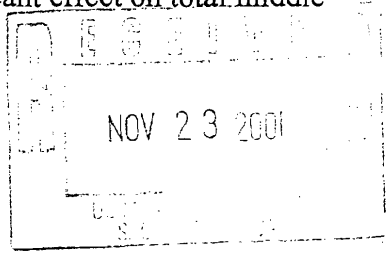
Scientific Justification for Unrelieved Potential Distress: The potential distress of individual housing in an unfamiliar environment is being relieved through a habituation procedure for our experimental animals. This leaves the actual noise exposure as our only unrelieved potential for distress as defined by the AWA. Alleviation of this potential distress through the use of anesthetics or analgesics is scientifically contraindicated for the following reasons.

General Considerations

a. Generalized anesthesia for a six hour duration would be medically contraindicated and in itself leads to a painful and distressful recovery period.
b. Animal models without anesthesia mimics human subjects under noise exposure better than the anesthetized animal.
c. Noise exposure should try to replicate the real world as much as possible; we typically are not exposed to noise in the drugged state. The administration of drugs to sound exposed animal's effects several important aspects of sound transduction in the inner ear and electrophysiological measurements of inner ear function. Because these confounded results from drugged animals can not be extended to human models, these drugged models are not used in hearing research. In the course of the Medline literature review going back over 20 years some 5500 abstracts involving loud sound exposure only about a dozen utilized anesthetized animals and in those cases the focus of the studies was to investigate the effects of those drugs on cochlear electrophysiological measurements.
d. Noise exposures in normal animals always result in significant variations in threshold shifts. These variations may result from a variety of factors overactive middle ear muscles, efferent feedback, state of the animal. Now there may be evidence that a drugged animal gives larger and more consistent thresholds shifts because of the elimination of the aforementioned variables.[1]

Specific Considerations

a. Sodium pento-barbital has been shown to have a significant effect on total middle ear impedance and on the shape of the tympanograms.[2]

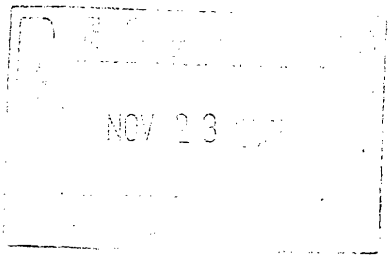


Column E Explanation cont.

b. The use of ketamine causes significant increases in distortion-product otoacoustic emissions. This result indicates that tonic activity levels in the cochlear efferents are reduced by the anesthetic effects which, could lead to greater damage due to loud sound exposure.[3, 4]
c. Isoflurane significantly attenuates auditory steady state response(which is a response of the brain to auditory stimuli) in a dose dependants matter.[5]

References

1) Popelar, J., et al. Effect of noise on auditory evoked responses in awake guinea pigs. Hearing Research. 26(3):239-47, 1987
2) Eames, B.L., et al. The role of the middle ear in acoustic trauma from impulses. Laryngoscope. 85(9):1582-92, 1975
3) Harel, N. et al. The effects of anesthesia on otoacoustic emissions. Hearing Research. 110(1-2):25-33
4) Puel, Jean-Luc, et al. Perspectives in inner ear pharmacology and clinical applications. In Cochlear pharmacology and noise trauma. Eds. D. Prasher and B. Canlon. NRN Publications. London; 1998
5) Plourde, G., et al. The effect of isoflurane on the steady state response and on consciousness in human volunteers. Anesthesiology. 89(4):844-51, 1998



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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

Lab

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 93-F-0007 CUSTOMER NO. 1201

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

USDA, AGRICULTURAL RESEARCH SERVICE
800 BUCHANAN STREET
ALBANY, CA 94710
(510) 559-5600

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	209	0	0	209
8. Rabbits	0	3	0	0	3
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
chicken	0	141	0	0	141
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.

NOV 21 2001

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-29-01

A FORM 7023 (Replaces VS FORM 18-23 (Oct 88), which is obsolete G 91)

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-F-0022 | CUSTOMER NO. 1204

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

60TH MEDICAL GROUP (AMC), MDSS/SGSE
101 BODIN CIRCLE
TRAVIS AFB, CA 94535

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	6		41		41
12. Other Farm Animals					
Goats	8		18		18
13. Other Animals					
Ferrets			10		10

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.

NOV 21 2001

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		13 Nov 01

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 2150.

See reverse side for additional information.

Laris

Interagency Report Control No 0180-DOA-AN

1-17-02

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 95-F-0001 CUSTOMER NO. 1205

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, Include Zip Code)*
Tripler Army Medical Center
ATTN: MCHK-CI (MAJ Goodwin)
Tripler AMC, HI 96859-5000
(808) 433-6709

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	1	31	0	9	40
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs	0	0	42	0	42
12. Other Farm Animals					
Goats	0	0	12	0	12
13. Other Animals					
Ferrets	0	0	5	0	5

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		9 Nov 01

APHIS FORM 7023 (AUG 91)

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

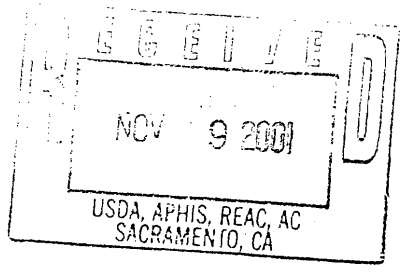
PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 95-F-001
Customer Number: 1205
Facility: Tripler Army Medical Center
MCHK-CI (ATTN: MAJ Goodwin)
Tripler AMC, HI 96859-5000
(808) 433-6709

Department of Clinical Investigation
MCHK-CI (ATTN: MAJ Goodwin)
Tripler AMC, HI 96869-5000



Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 95-F-001

2. Number 9 of animals used in this study.

3. Species (common name) guinea pigs of animals used in the study.

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

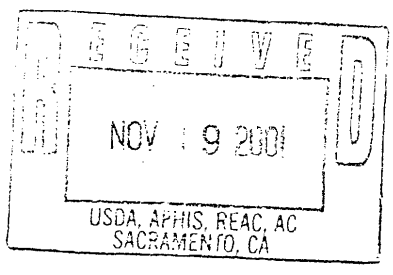
Starting at one to two days of age, neonatal guinea pigs are exposed to an atmosphere of 100% oxygen or 95% oxygen and 20 ppm nitric oxide for up to five days. Exposure to hyperoxia alone often produces respiratory distress after three to five days of exposure. Exposure to the combination of hyperoxia and nitric oxide may also result in respiratory distress. It should be noted that an early endpoint is used in this study: the guinea pigs are euthanized as soon as they progress beyond mild respiratory distress to develop cyanosis, lethargy, pallor, or an abnormal resting posture.

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)

The development of lung injury was a parameter being studied. Relief of any respiratory distress would have required removal from the altered atmosphere or anesthesia and intubation, both of which would have confounded the natural course of the pulmonary effects of hyperoxia and the potential mediating effects of nitric oxide. Furthermore, intubation and mechanical ventilation would potentially introduce barotrauma as a confounding source of lung injury. Literature searches failed to reveal an alternative to the use of animals to measure the whole animal physiological functions of interest.

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 _____ CFR _____



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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 12-R-0003 **CUSTOMER NO.** 167

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF NEW HAMPSHIRE
UNIVERSITY OF NEW HAMPSHIRE
THOMPSON HALL
DURHAM, NH 03824

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)*

UNIVERSITY OF NEW HAMPSHIRE
DURHAM, NH 03824

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		65			65
8. Rabbits			2		2
9. Non-Human Primates					
10. Sheep					
11. Pigs	79		52		52
12. Other Farm Animals					
13. Other Animals					
Whitetail Deer		16			16

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/18/2004

APHIS FORM 7023 **(AUG 91)** **(Replaces VS FORM 18-23 (Oct 88), which is obsolete**

PART 1 - HEADQUARTERS

APHIS Form 7023 Additional Reported Sites

The following additional sites have been reported by the facility. The reported sites have not been verified by APHIS and have been provided by the facility solely for completeness of the APHIS Form 7023 Annual Reporting submission.

Registration Number: 12-R-0003
Customer Number: 167
Facility: UNIVERSITY OF NEW HAMPSHIRE
UNIVERSITY OF NEW HAMPSHIRE
THOMPSON HALL
DURHAM, NH 03824

Animal & Nutritional Sciences Contact
Burley Dermeritt Farm
Brentwood Fram Site 007
Lee, NH 03824
Naimal Resources Office Contact
Rudman Hall
Human Nutrition Center Isolation Building Site 0101
Durham, NH 03824

ANNUAL REPORT OF RESEARCH FACILITY (addendum to report submitted electronically on 11/18/2004)	1. REGISTRATION NO. 12-R-0003	
	2. HEADQUARTERS RESEARCH FACILITY University of New Hampshire Office of Sponsored Research 107 Service Building Durham, NH 03824 Status: Active	

REPORT OF IACUC-APPROVED EXCEPTION

UNH IACUC PROTOCOL NUMBER:	010701
ORIGINAL APPROVAL DATE:	August 7, 2001
PROTOCOL CLOSURE DATE:	July 21, 2004
SPECIES:	Whitetail Deer
ANIMAL NUMBERS (for exception):	4

DESCRIPTION:

The animals were fasted for 48 hours for metabolic testing. Water was available ad lib, and the animals were monitored during the fast by the University of New Hampshire Animal Resources Office.

This protocol was reviewed and approved by the University of New Hampshire Animal Care and Use Committee.

This report is submitted in compliance with USDA required procedure.

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 2150 2/5

See reverse side for additional information

Interagency Report Control No. 0180-00A-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS *include Zip Code)* 14-R-0009, Cust Id 105

USDA

(see attached)

BOSTON UNIVERSITY MEDICAL SCHOOL
80 E. CONCORD STREET
BOSTON, MA 02118

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)*

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.)*

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	Ø	Ø	Ø	Ø	Ø
5. Cats	Ø	Ø	14	Ø	14
6. Guinea Pigs	Ø	108	Ø	Ø	108
7. Hamsters	8	Ø	Ø	Ø	Ø
8. Rabbits	Ø	178	246	Ø	424
9. Non-human Primates	34	Ø	60	Ø	60
10. Sheep	Ø	Ø	Ø	Ø	Ø
11. Pigs	2	2	62	Ø	64
12. Other Farm Animals	Ø	Ø	Ø	Ø	Ø
poikilotherms	400	460	38	Ø	498
13. Other Animals Ferrets	Ø	Ø	4	Ø	4
mice	5244	12,629	5459	Ø	18,088
rats	209	7177	6969	Ø	14,146
chinchillas	Ø	Ø	220	25	245

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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
		11/29/00

APHIS FORM 7023
(AUG 91)

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

PART 1 - HEADQUARTERS

This report is required by law (7 USC 2143). Failure to report ... result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 14-R-0036 CUSTOMER NO. 515

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF MASSACHUSETTS AT AMHERST
ANIMAL CARE OFFICE, GRAD. SCH.
512 GOODELL BUILDING
AMHERST, MA 01003
(413) 545-0666

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters ,Syrian	248	36	758	0	1042
8. Rabbits	0	6	88	0	94
9. Non-Human Primates	0	8	0	0	8
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Horses	0	0	16	0	16
CATTLE 13. Other Animals	1	2	1	0	4
Hamster,Siberian	399	0	79	0	478
Voles, Prarie	600	100	500	0	1200
Voles, Pine	30	0	0	0	30

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/29/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.	CUSTOMER NO.	FORM APPROVED
14-R-0036	515	OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF MASSACHUSETTS AT AMHERST
ANIMAL CARE OFFICE, GRAD. SCH.
512 GOODELL BUILDING
AMHERST, MA 01003
(413) 545-0666

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Gerbils	15	0	54	0	69
Beaver	0	0	30	0	30
White tail deer	0	0	27	0	27
Virginia Opossum	0	30	0	0	30
FISHING CATS:					
Darwin's Fox	0	25	0	0	25
Grey Fox	0	19	0	0	19
Red-back vole	0	4	0	0	4
Deer mouse	0	1	0	0	1

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/29/01

APHIS FORM 7023A (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

Summary of Exceptions to the Regulations and Standards
Specified and Explained by the Principal Investigator and Approved by the IACUC

1. In a study involving Syrian hamsters, the researcher submitted a memorandum of explanation to the IACUC regarding a change in the cleaning schedule for cages in which his hamsters are housed for particular studies approved previously by the IACUC. This relates to 9 CFR, Ch. 1, Part 3, Subpart B, 3.31,a. This matter was discussed and approved by the IACUC on August 20, 2001. The measure is supported by a policy statement of the Society for the Research on Biological Rhythms which appeared in the Journal of Biological Rhythms, Vol, 8, pp. 97-106 (1993) which outlines and explains modifications of normal observance, cleanliness/sanitation, and food and water provision procedures for rodents in circadian rhythm studies. The change involved delaying cage cleaning because the stimulus of the cleaning process (new cage, fresh bedding) disrupts free running activity levels developed during the study. These activity levels must be measured over several weeks in the same (unchanged) cage environment. It was agreed that the researcher will monitor closely the cages during these particular studies to insure the environments of the hamsters and mice will be satisfactory as possible until the data collections are completed. Such observations must be conducted under very dim red illumination. It was agreed by the IACUC and the Director of Animal Care that inactive animals will be visually checked to make sure they are not ill or in distress. Healthy mice and hamsters run many revolutions on a wheel each night, and computer records indicating robust activity are considered adequate verification of each animal's well being. A total of 120 hamsters and 80 knockout (graft recipient) mice were assigned to these studies, but the studies are performed on groups of 12-26 hamsters and 12-36 mice at a time.

2. On April 30, 2001, the IACUC approved a request from a researcher to make his own sodium pentobarbital solutions because the solutions were not commercially available at the time. Preparation was in accord with the Animal Care Director's message of April 20, 2001. The researcher expects that his surgical mortality rate will remain insignificant, <5%. The preparation at the bench is as follows:
   - The solution must be prepared (and used) aseptically/sterilely as any material administered to any animal must be.
   - Prepare as sterile filtered (0.2 micron) into a sterile vial with sterile stopper.
   - Label as thoroughly as possible in order to minimize any confusion. Include the fact that it was prepared sterilely by the lab for use in animals, date of preparation, initials of preparer, and concentration.
   - "Outcomes" are that the material is effective as an anesthetic agent (or in some cases for euthanasia), so in that regard, surgical/post-op/nursing/euthanasia records and all necessary notations reflecting the monitoring of the animals will provide evidence that the material is effective and safe.
   - Store all controlled substances in locked cabinets with limited access by lab personnel.
   - Maintain all records documenting acquisition of starting material, preparation, and use as for any controlled substance.

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 21!

NOV 2 4 2004

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 14-R-0082

CUSTOMER NUMBER: 140

FORM APPROVED
OMB NO. 0579-0036

Tufts- New England Medical Center, Inc.
171 Harrison Avenue, Nemc #112
Boston, MA 02111

Telephone: (617) -636-5615

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	49	0	49
5. Cats	0	0	2	0	2
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	22	0	22
8. Rabbits	0	13	172	0	185
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	124	0	124
12. Other Farm Animals	0	0	6	0	6
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11.22.04

APHIS F 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

Tufts University Health Sciences campus and Tufts-New England Medical Center locations approved for animal use (unregulated species included in location report)

Centralized Housing Facilities
Stearns-Arnold
Ziskind

Satellite Housing Facilities
Tupper
75 Kneeland

Research Laboratories
M&V
South Cove
Stearns-Arnold
Tupper
Ziskind
Jaharis
75 Kneeland

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 21!

NOV 2 6 2004

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 14-R-0096

CUSTOMER NUMBER: 146

FORM APPROVED
OMB NO. 0579-0036

Mc Lean Hospital Corporation
115 Mill Street
Belmont, MA 02478

Telephone: (617) -855-2000

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates			139		139
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-22-2004

APHIS FORM 7023 (Replac FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

The following is a list of Animal Care Facility locations on the McLean Hospital Corporation campus:

Mailman Research Center (MRC) Animal Care Facility: MRC, Ground Floor

The Alcohol and Drug Abuse Research Center (ADARC) Primate Facility: Oaks I and II.

The Alcohol and Drug Abuse Research Center (ADARC) Small Animal Facility: Oaks IV.

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 14-R-0128
CUSTOMER NUMBER: 156

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY
Harvard University
Faculty of Arts & Sciences
24 University Hall
Cambridge, MA 02138
Telephone: 617-496-3992

DEC 01 2004

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*) - See Attached Listing.

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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. Numbers 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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	1	0	4	0	4
9. Non-human Primates	0	35	0	0	35
10. Sheep	0	0	16	0	16
11. Pigs	0	0	8	0	8
12. Other Farm Animals					
Goats	18	2	7	0	9
13. Other Animals					
Bats	0	48	5	0	53

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	DATE SIGNED
		11/23/04

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 14-R-0128
CUSTOMER NUMBER: 156

FORM APPROVED
OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY
(*TYPE OR PRINT*)

2. HEADQUARTERS RESEARCH FACILITY
Harvard University
Faculty of Arts & Sciences
24 University Hall
Cambridge, MA 02138
Telephone: 617-496-3992

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 — 12. &/OR 13. Other (*List by Species*)	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. Numbers 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)
13. Other ... continued					
Birds (wild caught)	2	0	11	0	11
Chinchillas	1	0	0	0	0
Emus	0	0	15	0	15
Ferret, European	1	0	0	0	0
Guinea fowl	0	0	8	0	8
Hedgehog, African	1	0	0	0	0
Opossum	1	0	0	1	1
Owl, screech	1	0	0	0	0
Tinamous	0	0	1	0	1
Wallabies	0	0	2	0	2

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	DATE SIGNED
		11/23/04

Explanation for Opossum Appearing in Category E:

On Friday, 25 June 2004, one of the animals, an opossum, used only for display/teaching purposes in the Harvard Museum of Natural History, was discovered dead in her cage. Sometime during the previous night apparently she had made a hole in her sleep towel and asphyxiated herself. Obviously she died without the assistance of pain relieving drugs. The animals used in this program (among them the above listed chinchilla, ferret, hedgehog, rabbit, and replacement opossum) are cared for under research animal standards but are treated as pets; the teaching program staff was devastated by the nature of her loss. This incident was reported to our USDA inspector [redacted] shortly thereafter. [redacted] consulted with the regional office and informed Harvard that we had fulfilled our responsibilities in reporting the death but that no further action was required; it was categorized as an accident. To prevent a repeat of the above described event, the Museum staff now carefully inspects all sleep towels before dispensing them to assure there are no tears or worn areas.

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 21!

NOV 2 9 2004

See attached form for additional information.

Interagency Report Control No.: 042

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 14-R-0150

CUSTOMER NUMBER: 10717

FORM APPROVED
OMB NO. 0579-0036

Alkermes Inc
88 Sidney St
Cambridge, MA 02139

Telephone: (617) -494-0171

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs			164	196	360
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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)

AL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/23/04

3 (OCT 88), which is obsolete.)

(AUG 91)

Attachment A

Explanation re guinea pigs not receiving anaesthesia or analgesia (Column E)

Animals not receiving anaesthesia or analgesia were used in a citric acid induced cough procedure under Alkermes IACUC protocol [redacted] "Antitussive and bronchorelaxant effects of local anesthetics and bronchodilators alone and in combination, in guinea pigs." The actual citric acid challenges that evoke cough have never been conducted under anesthesia, either in our laboratory or in the reported literature. The two primary reasons for this are: 1) In order to mimic the clinical setting, where volunteers for studies remain conscious during tussigenic challenges, as closely as possible and 2) Afferent impulses triggering cough appear to be mediated through at least two subtypes of airway sensory fibers, Aδ "cough receptors," and slowly-conducting C fibers. While a number of stimuli known to evoke cough in humans and guinea pigs (e.g., capsaicin, bradykinin, SO_2) appear to selectively activate C fibers, these agents fail to produce a cough in an anesthetized guinea pig (reviewed in Canning, *Pulm Pharm & Ther*, 2002). This means the cough in anesthetized guinea pigs is driven entirely by the "cough receptors." While this setting could be informative when investigating the role of the "cough receptors," it does not reflect the normal physiology of cough.

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 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **CERTIFICATE NUMBER:** 14-R-0162
CUSTOMER NUMBER: 17008

FORM APPROVED
OMB NO. 0579-0036

Nucryst Pharmaceuticals
50 Audubon Rd
Suite B
Wakefield, MA 01880

Telephone: (781) -246-6053

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		456			456
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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	INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
			11/19/01

APHIS FORM 7023
(AUG 91)

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

NUCRYST PHARMACEUTICALS

JAN 2 4 2005

January 6, 2005

Elizabeth Goldentyer, DVM
Regional Director, Animal Care
USDA-APHIS Eastern Regional Office
920 Main Campus Drive
Suite 200, Unit 3040
Raleigh, NC 27606-5210
Ph. 919-716-5532

Subject: Annual Report of Research Facility for 1 Oct 2003 through 30 Sept 2004
USDA Registration # 14-R-0162

Dear Dr.Goldentyer:

We are providing the following explanation in regards to our annual statistical report of animal research activities at NUCRYST Pharmaceuticals. The use of guinea pigs reported in USDA Category C (minimal, momentary, or no animal pain &/or distress) is explained by the sequence of events outlined in the following sections.

- Protocol [redacted] was reviewed and approved by the NUCRYST IACUC on 10 August 04. This protocol involved guinea pig skin sensitization at 4 sites on the back using dinitro-chlorobenzene (DNCB) and subsequent topical treatment of skin lesions with our proprietary compounds containing nanocrystalline silver. The guinea pigs proposed for use in the protocol were categorized in USDA Category D due to the provision of anesthesia for skin biopsies during the resolution phase of the skin lesions.
- As the study progressed, the need for skin biopsies during the study was replaced by post-mortem collection of tissues. Thus, the proposed anesthesia was not utilized.
- Protocol [redacted] was reviewed by the USDA during an inspection on 13 July 2004. Although there were no guinea pigs on study at the time of this inspection, the inspector indicated that animals had had severe skin lesions and that analgesics had not been administered. The USDA inspector indicated that protocol [redacted] needed to be re-reviewed by the IACUC before 27 July 04. The USDA inspector also indicated that the guinea pigs used in [redacted] during the period of the previous annual report (2002-03) needed to be re-categorized in USDA Category E.

50 Audubon Road, Suite B, Wakefield, MA 01880 Telephone: 781-246-6044 Fax: 781-246-6032

- In conformance to the USDA inspector's request, the NUCRYST IACUC convened a meeting on 15 July 2004 to discuss the level of pain/distress associated with the use of guinea pigs in protocol
  All IACUC members but one were in attendance. There was extensive discussion of the nature of the skin lesions, the possible side-effects of analgesic agents, and the integrity of the scientific value of the studies. The Principal Investigator had prepared a proposed pilot study to test the efficacy and side-effects of analgesia in the skin lesion model. Based on previous discussions with the Attending Veterinarian, the analgesic agent buprenorphine was proposed as the analgesic agent of choice due to its potency and duration of action. The IACUC voted (with the abstaining) in favor of having the Principal Investigator conduct a pilot study that included groups of guinea pigs both with and without analgesic treatment. The animals would be closely monitored during the study to assess any beneficial or adverse effects of the analgesic treatment. The IACUC also agreed that the guinea pigs reported on the previous annual report to USDA would be re-categorized into USDA Category E in compliance with the USDA inspector's request.
- The pilot study to test the effects of analgesic treatment on guinea pigs in the skin sensitization model was conducted 24 August through 8 September 04. Buprenorphine was administered at 0.04 mg/kg SC bid to guinea pigs in the analgesic treatment groups starting on day 11 (skin lesion initiation) until day 16 (euthanasia at conclusion of study). Data were collected and analyzed.
- On 1 October 2004, the IACUC met to review the results of the pilot study that included the use of buprenorphine as an analgesic for guinea pigs with skin lesions. Based on the review of the data collected (see appended materials) during the pilot project, the following conclusions were reached:
  - There were no statistically significant differences in weight gain for guinea pigs with and without buprenorphine treatment. However, the guinea pigs that received buprenorphine had consistently lower body weights than animals that did not receive analgesic.
  - Guinea pigs that received buprenorphine at 0.04 mg/kg bid were noted to be dull and lethargic. Their behavior was notably different from animals that did not receive the analgesic.
  - There were no statistically significant differences in lesion scores for guinea pigs with and without buprenorphine treatment. However, the lesion erythema and edema scores for guinea pigs that received analgesic were consistently lower than scores for animals that did not receive analgesic.
  - There was concern based on published literature presented to the IACUC (see appended materials) that buprenorphine had anti-inflammatory effects that could effect the scientific outcome of the skin lesion model and the subsequent testing of NUCRYST's proprietary therapeutic compounds. Although buprenorphine was considered the best analgesic drug candidate for the purposes of this study in part based on its minimal anti-inflammatory action, subsequent closer examination of the scientific literature indicated that buprenorphine does have immuno-modulatory properties.

  The use of buprenorphine as an analgesic agent was deemed non-beneficial and perhaps even detrimental for the animals in this project. The use of acetaminophen was discussed but dismissed due to its limited potency, possible hepatotoxicity, short duration of action, and unknown mechanism of action. The substitution of non-steroidal anti-inflammatory agents (aspirin, ibuprofen, ketoprofen, etc.) was considered contrary to the goals of the study, since these agents have significant effects on the inflammatory process that is being evaluated.

50 Audubon Road, Suite B, Wakefield, MA 01880 Telephone: 781·224·1444 Fax: 781·246·6002

In order to better understand the symptoms experienced by the guinea pigs under protocol the IACUC of NUCRYST Pharmaceuticals has sought the expert opinion of [redacted] a board-certified dermatologist, on the human correlate to the skin lesions that are produced in guinea pigs used in protocol [redacted] As noted by [redacted] in his analysis (see appended letter), the skin lesions produced by DNCB application to guinea pigs correlate roughly with the human skin condition known as acute contact hypersensitivity that occurs in individuals allergic to poison ivy. According to [redacted] patients that have this condition (with a severity similar to that of guinea pigs of grade 3 or grade 4) typically present to the clinic complaining of itching, or occasionally of a stinging sensation, but seldom report pain due to these skin lesions. The standard treatment for such patients, according to [redacted] is treatment with anti-itch or anti-pruritic agents. Analgesics are generally not given to these patients. If we are to extrapolate from this evaluation, it is likely that while the animals are probably experiencing some degree of itching or stinging, they are probably not experiencing pain. Based on the clinical condition of animals in all previous studies and the evidence collected in the pilot study, the IACUC voted to categorize the use of guinea pigs in protocol [redacted] l in USDA Category C. [redacted] abstained from voting. The annual report to USDA for animal use during 2003-04 included the use of 788 guinea pigs in USDA Category C in compliance with the decision of the NUCRYST Pharmaceuticals IACUC.

All of the IACUC actions noted above have become part of the official institutional records and are available for inspection at NUCRYST.

NUCRYST Pharmaceuticals is providing the information outlined above to better explain both the process and the rationale used by the IACUC in the assessment of animal pain/distress in protocol # 02-001. Please contact me at 781-246-6044 or [redacted] if any additional explanation regarding our 2003-2004 report is required.

Sincerely,

06-JAN-2005

Enclosures:

- Copy of NUCRYST's Annual Report to USDA for 03-04
- Letter from dermatologist [redacted] on nature of skin lesion pain/distress
- Synopsis of literature searches performed on non-mammalian alternatives to the use of guinea pig and on the compatibility of opioids and inflammatory research.
- Sample data from pilot studies on the impact of buprenorphine on guinea pig model of contact dermatitis

50 Audubon Road, Suite B, Wakefield, MA 01880 Telephone: 781-224-1444 Fax: 781-246-6002

Synopses of literature searches performed for Contact Dermatitis Study

Several literature searches were performed, both using the Pubmed search engine that queries the Medline database of the National Library of Medicine. Searches were performed 13-19 August 2004, and covered literature dating from mid-1960s to the present (that is, the entire scope of the Medline database).

The first literature search was intended to determine whether previous research had discovered an *in vitro* alternative to the use of animals in the study of contact dermatitis. In order to be a viable alternative to *in vivo* contact dermatitis, an *in vitro* model should have the following characteristics: i) it should allow an assessment of the concerted action of all cell types that are likely to be involved in contact dermatitis, including but not limited to epithelium, macrophages, neutrophils, lymphocytes, and dendritic cells (Langerhans cells); ii) it should persist and/or develop in a chronic fashion that mimics the persistent nature of *in vivo* contact dermatitis; and iii) it should provide some method for accounting for the interplay between immunological, hormonal, and neural contributions to contact dermatitis. There are no reports available on *in vitro* or non-mammalian *in vivo* models of allergic contact dermatitis that meet all of these criteria, as determined by the following literature searches:

A search performed on 13 August, 2004 using the following sets of search parameters yielded the results described to the right of each set of parameters:

Search Parameters	**Results**
non-animal models for allergic contact dermatitis	none
anti-inflammatory activity in *in vitro* models of allergic contact dermatitis	Four results. One of these articles reviews the results of studies done using a pig and rodent models (Stuetz A, et al., Semin Cutan Med Surg. 2001. 20(4):233-41), two others report results obtained using rodent models (Imming P, et al. Inflamm Res. 2001. 50(7):371-4; Zunic M, et al. J Invest Dermatol. 1998. 111(1):77-82), and one reports *in vitro* studies done with cloned T cells, and with T cell-, dendritic cell-, and mast cell lines (Grassberger M, et al. Br J Dermatol. 1999. 141(2):264-73). Thus, only one of these articles reports exclusively *in vitro* studies. Additionally, the data from this one *in vitro* study are difficult to extrapolate to the context of intact, live skin.

A search performed on 18 August, 2004 using the following sets of search parameters yielded the results described to the right of each set of parameters:

Search Parameters [ti] searches for keyword within title	**Results**
Reptilian AND contact AND dermatitis	none
reptile AND contact[ti] AND dermatitis[ti]	none
insect AND contact[ti] AND dermatitis[ti]	22 results. All pertaining to contact dermatitis in humans, mostly CAUSED BY insects
amphibian AND contact[ti] AND dermatitis[ti]	1 result, pertaining to contact dermatitis in a human CAUSED BY toad venom (venenum bufonis)
vitro[ti] AND contact[ti] AND dermatitis[ti]	10 results total. One article of interest (Fraginals R, et al. Arch Dermatol Res. 1990. 282(7): 455-8.) compared mouse ear thickness readings (*in vivo*) to *in vitro* lymphocyte proliferation assays. Correlation was good for all but one allergen, but this study included only the contribution by cells of lymphoid lineage. While useful for studying the nature of allergic sensitization, this model would not be suitable for studying the entire inflammatory process or the efficacy of anti-inflammatory compounds.

Given the limitations of *in vitro* testing methods, and the lack of a suitable non-mammalian animal model, it is apparent that the use of a mammalian animal model will be necessary. Animals used for this purpose may suffer pain or distress due to the experimentally induced dermatitis. Therefore, animals will be provided with an analgesic, *assuming* that an analgesic drug and a dosing regiment can be identified which will not interfere with the normal course of the disease being studied. Since contact dermatitis is an inflammatory disease, it will be imperative that the analgesic used possesses little or no intrinsic anti-inflammatory properties. To begin to investigate the known anti-inflammatory properties of analgesics, and to predict their likely effect on our guinea pig model of contact dermatitis, a second literature search was carried out.

A search performed on 19 August, 2004 using the following sets of search parameters yielded the results described to the right of each set of parameters:

Search Parameters [ti] searches for keyword within title	**Results**
analgesic[ti] AND contact[ti] AND dermatitis[ti]	Two results, both pertaining to contact dermatits CAUSED BY analgesics
buprenorphine[ti] AND contact[ti] AND dermatitis[ti]	none
buprenorphine AND contact[ti] AND dermatitis[ti]	none
buprenorphine AND contact AND dermatitis	One result: Elliott JC, et al. J Invest Dermatol. 2003. 121(5):1053-9. The report contains data that show contact dermatitis is modulated *in vivo* by mu-opioids morphine, etorphine, and buprenorphine. This effect is more pronounced in female animals than in male animals.

Data reported in the last article cited (Elliott, JC, 2003) would seem to contraindicate the use of opioids in animal models of contact dermatitis. Addition contraindication for the use of such analgesics can be found in reports published over the past ten years (Van Loveren H, et al. Lab Anim. 1994. 28(4):355-63; Volker D, et al. Lab Anim. 2000. 34(4):423-9; Carrigan KA, et al. Int Immunopharmacol. 2004. 4(3):419-28). Collectively, these articles report experimental data suggesting that immune function can be altered by an anti-inflammatory activity that is intrinsic to some opioids. However, it is still possible that the results of these previous studies may not extend to the guinea pig model of contact dermatitis that we are employing. Therefore, we intend to pursue a series of pilot experiments designed to ascertain whether buprenorphine would have confounding effects if used in our model of contact dermatitis. If the results of these pilot studies indicate that analgesics can be used without compromising the validity of our experiments, than we will provide our animal subjects with analgesics throughout future experiments.

USDA/Appendix

Summary of the Experiment :

Aim: To check if analgesics (Buprenorphine) interfere in the Allergic Contact Dermatitis experimental conditions.

Treatment groups:

Animals: Guinea pig (Hartley strain), sex: female.
Allergic contact dermatitis was induced by sensitizing and challenging with 5% dinitrochlorobenzene (DNCB). One day after the challenge, the animals were evaluated for the presence of clinical development of dermatitis and divided into groups of 12 animals. The animals were treated with test creams once daily for five days
Number :(n = 12/group; 8 animals provided with analgesic and 4 without analgesic)
Analgesic used in this study: Buprenorphine (Buprenex) (0.04mg/kg body weight; twice/day)

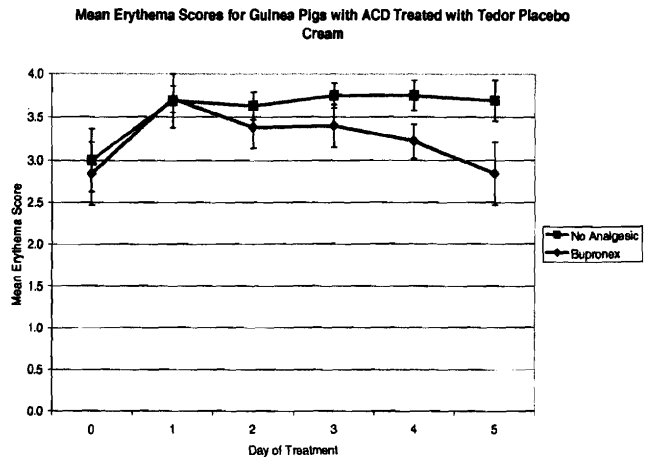
Groups:
1. Placebo
2. No treatment
3. 1.0% cream

RESULTS:

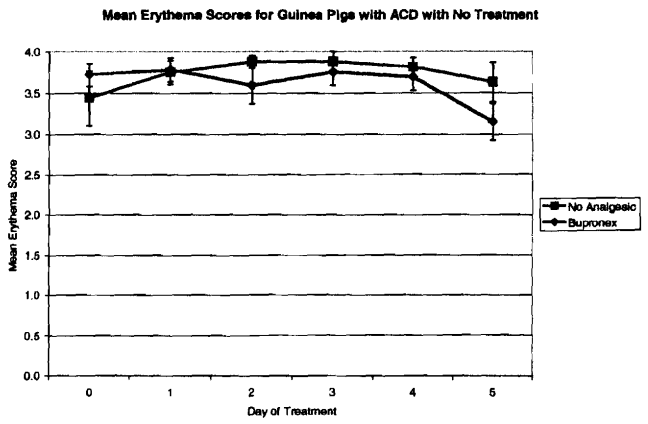
Role of analgesic on reduction of dermatitis:
Eight animals in each group were provided with analgesic (Buprenorphine) twice a day and four animals were not provided with analgesic.
All the animals treated with analgesic looked lethargic, compared to animals without analgesic. In the placebo and no treatment groups, there was slight difference in reduction of erythema between two groups (Figure 1 A, B). Reduction of erythema was better in the group of animals provided with analgesic than the group not provided with analgesic. However this difference was not statistically significant.
In the group treated with our test compound (1% cream), there was slight difference in the reduction of erythema in between analgesic and non-analgesic groups (Figure 2). In the group treated with 1% cream, the difference was not statistically significant (Figure 2)

Figure 1

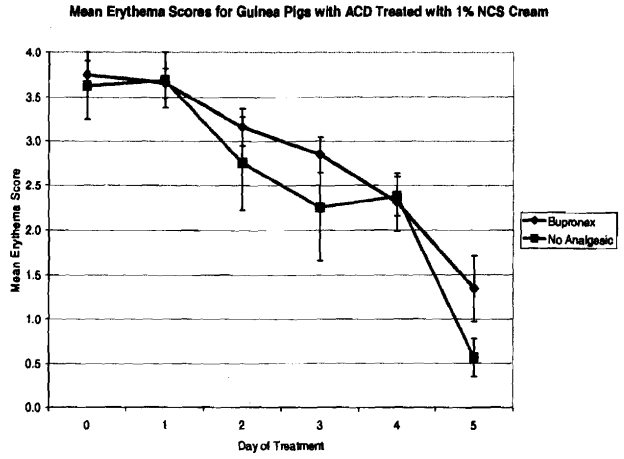
(1A)Placebo Group:



(1B) No Treatment Group:



2. 1% NCS

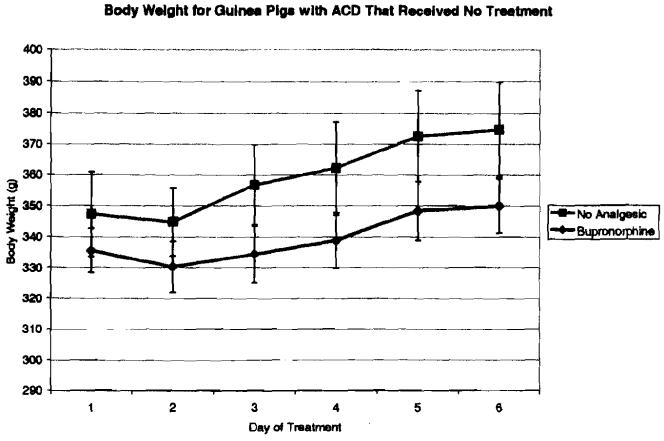


Role of analgesics on changes in body weight of animals:

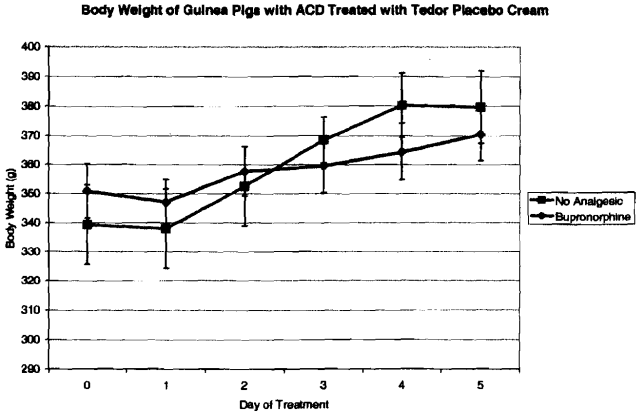
Animals in all the groups slightly reduced body weight after one day of induction of dermatitis and gradually the body weight was increased there after. There was no statistically significant difference in daily body weight of animals in the analgesic and non-analgesic groups (Figure 3, A, B, C).

Figure 3 (Body weight).

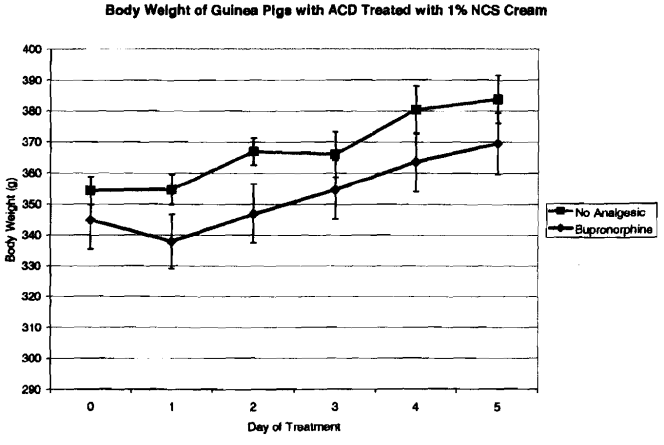
3A. No Treatment Group:



3B. Placebo Group:



3C. 1% Nanocrystalline Silver Cream Group:



Conclusion:

The above results demonstrated that there is no statistically significant difference in reduction of dermatitis when using analgesic. However there is a decrease in the mean erythema and edema scores in the control groups that were given analgesic. It is believed that the analgesic may interfere in the pathogenesis of allergic contact dermatitis in this model.

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 2150.

See reverse side for additional information.

Interagency Animal Welfare Committee 0580-00A-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

NOV 2-8

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 21-R-0106

FORM APPROVED OMB NO. 0579-003

2. HEADQUARTERS ADDRESS (Include Zip Code) Name and Address, as registered with USDA

Astra Arcus, USA, Inc (AstraZeneca)
P.O. Box 20890
Rochester, NY 14602

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

FACILITY LOCATIONS (Sites)	
AstraZeneca, 755 Jefferson Rd.	AstraZeneca, One Innovation Dr.
Rochester, NY 14623	Worcester, MA 01605

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		178		101	279
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

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
		11/28/00

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

Registration Number 21-R-0106
Astra Arcus USA, Inc.
P.O. Box 20890
Rochester, NY 14602

The principal behind the procedure is that inescapable exposure to an aversive stimulus, such as electric shock, later impairs animals' ability to learn to escape or avoid presentation of that aversive stimulus when ample opportunity to do so is provided. Such impairment is thought to model aspects of major depression in humans, and is considered one of the most valid animal models of the disorder. All currently useful antidepressant drugs have some efficacy in the model, administration of which following exposure to the inescapable aversive stimulus reverses the impairment in learning to avoid or escape the stimulus. Analgesic or tranquilizing drugs would interfere with the effect of administration of the aversive stimulus, and thus not allow for the accurate determination of efficacy of the candidate antidepressant. The use of this procedure is currently the best predictor of clinical efficacy in humans, and is usually reserved for candidate drugs that are being considered for clinical testing.

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 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 21-R-0173
CUSTOMER NUMBER: 6799

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Liberty Research Inc
P.O. Box 107
State Route 17c
Waverly, NY 14892

Telephone: (607) -565-8131

NOV 0 8 2004

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this repor	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	374	142	28	544
5. Cats	0	761	206	93	1060
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 *(Type or Print)*	DATE SIGNED
		11/4/04

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 21 – R – 0173
2. Number 93 of animals used in this study.
3. Species (common name) cat of animals used in the study.
4. Explain the procedure producing pain and/or distress.

The clinical symptoms and signs of Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Virus.

5. Provide a scientific justification why pain and or distress could not be relieve. 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)

9 CFR Subchapter E Section 113.203, 113.210, and 113.211 outline the requirements needed to license a product such as that being tested in this study. Clinical disease must be allowed to develop to prove the potency of the challenge virus, which in turn proves the efficiency of the vaccine.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specified section number (e.g., AHPIS, 9 CFR 113.102):

Agency APHIS 9 CFR 113.203, 113.210, 113.211

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 21 – R – 0173
2. Number 28 of animals used in this study.
3. Species (common name) dog of animals used in the study.
4. Explain the procedure producing pain and/or distress.

The clinical symptoms and signs of Canine Distemper, Canine Adenovirus, Canine Parainfluenza and Canine Parvovirus viruses.

5. Provide a scientific justification why pain and or distress could not be relieve. 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)

9 CFR Subchapter E Section 113.305, 113.306, 113.316 and 113.317 outline the requirements needed to license a product such as that being tested in this study. Clinical disease must be allowed to develop to prove the potency of the challenge virus, which in turn proves the efficiency of the vaccine.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specified section number (e.g., AHPIS, 9 CFR 113.102):

Agency APHIS 9 CFR 113.305, 113.306, 113.316, 113.317

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 21(

NOV 1 9 2004

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0006
CUSTOMER NUMBER: 169

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Ortho Pharmaceutical Corporation
Johnson & Johnson Pharmaceutical Rsrch & Dev Llc
P O Box 300 Route 202 South
Raritan, NJ 08869

Telephone: (908) -704-4310

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquillzing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	184	202	139	207	548
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	51	1256	0	1307
7. Hamsters	0	0	607	293	900
8. Rabbits	4	0	147	0	147
9. Non-human Primates	14	0	50	17	67
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11-18-04

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

ATTACHMENT 1

USDA ANNUAL REPORT (2003-2004)

Registration #: 22-R- 0006

Animals Listed in Category E

During the reporting period, Johnson & Johnson Pharmaceutical Research & Development, L.L.C Institutional Animal Care and Use Committee (IACUC) approved the use of animals in Category E as follows:

SPECIES	NUMBER	PROCEDURE/JUSTIFICATION
Dogs Non-Human Primates	207 17	Single and repeat dose Pharmacokinetic/Toxicology studies as part of the Preclinical package submitted to the FDA for review and eventual drug approval. In these studies, animals may occasionally show mild emesis and short-term loss of appetite. It is important to determine if these clinical signs are reversible, as is often the case. Opioid analgesics alter GI motility and would be contraindicated. 1,2,3
Hamsters	293	Studies are used for evaluating anti-inflammatory compounds. Dorsal sub-cutaneous air pouch and paw edema models are utilized. 1

1 Administration of anesthetics, analgesics or tranquilizing drugs must be withheld so as not to invalidate the evaluation of test compounds.

2 Preclinical toxicology and drug metabolism/pharmacokinetic studies are required in nonhuman species by the Food and Drug Administration, Good Laboratory Practice Regulations – CFR 21, Part 58 (Code of Conduct).

3 Spied, L.H., Lunley, C.E. and S.R. Walker. "Harmonization of Guidelines for Toxicity Testing of Pharmaceuticals by 1992." Regulatory Toxicology and Pharmacology. Vol 12, pp 179-211 (1990).

Attachment 2

USDA ANNUAL REPORT (2003-2004)

Registration #: 22-R- 0006

The following animals, included in this report, were reported on previous USDA Reports under License: 22-R-0006.

SPECIES	CATEGORY B	CATEGORY C	CATEGORY D	CATEGORY E
DOGS	16	27	130	40
GUINEA PIGS	0	0	235	0
RABBITS	4	0	59	0
NON-HUMAN PRIMATES	14	0	45	15

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 21

NOV 26 2003

See attached form for additional information.

Interagency Report Control No.: 4CT

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0036
CUSTOMER NUMBER: 181

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Schering Corporation
Schering-Plough Research Inst.
2015 Galloping Hill Road
Kenilworth, NJ 07033

Telephone: (908) -298-4000

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	94	151	3	248
5. Cats	0	0	27	0	27
6. Guinea Pigs	0	4381	2435	0	6816
7. Hamsters	0	0	110	0	110
8. Rabbits	0	615	352	11	978
9. Non-human Primates	95	470	413	8	891
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Gerbils	0	48	4272	0	4320

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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)

S	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/25/03

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

Customer ID and Site Address: Site 1

ID: 181

2000 Galloping Hill Rd
Kenilworth, 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

Registration Number: 22-R-0036

November 22, 2003

Elizabeth Goldentyer, DVM
UNITED STATES DEPARTMENT OF AGRICULTURE
Animal and Plan 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.

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 2150 additional information. 0186-0UA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

2. HEADQU *include 2* 22-R-0115, Cust Id 714 *d with USDA.*
GEOFFREY R ROBBINS
COSOMOPOLITAN SAFETY EVALUATION, INC.
P.O. BOX 71
LAFAYETTE, NJ 07848

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)*

33A Broad Street, Branchville, N.J. 07826

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					0
5. Cats					0
6. Guinea Pigs		62	0	0	62
7. Hamsters					0
8. Rabbits		58	0	23	81
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		9 Oct 00

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 22-R-0115

2. Number 23 **of animals used in this study.** year.

3. Species (common name) Rabbit **of animals used in this study.** year.

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

Primary (Acute) Eye Irritation. The test substance (0.1 ml) is placed in the cul-de-sac next to the inner canthus and the eye is held closed for one second. By regulation the eye is not washed for 24 hours unless there is severe distress. Vocalization or severe struggling on application would be signs indicative of pain, but these signs were not seen in these studies.

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 question 6 below)

Rabbits usually do not show signs of severe pain or distress early in the studies. The protocol provides for the possible use of local anesthetic. Later (>5 days) on keratoconus and/or perforation are regarded as being distressing and any affected animals immediately underwent euthanasia.

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 EPA OPPTS **CFR** 870.2400

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 22-R-0133 **CUSTOMER NO.** 406

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

PUBLIC HEALTH RESEARCH INSTITUTE
225 WARREN STREET
NEWARK, NJ 07103
(973) 972-9150

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	1	57	0	58
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	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, 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 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)

INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/10/04

APHIS FORM 7023 **(AUG 91)**

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

PART 1 - HEADQUARTERS

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 21!

NOV 2 6 2004

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **CERTIFICATE NUMBER:** 23-R-0033

CUSTOMER NUMBER: 337

FORM APPROVED
OMB NO. 0579-0036

Childrens Hospital Of Philadelphia
Joseph Stokes Jr Res Inst
3516 Civic Center Blvd.
Philadelphia, PA 19104

Telephone: (215) -590-3800

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	30	0	0	30
7. Hamsters	0	0	0	0	0
8. Rabbits	0	50	90	0	140
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	9	0	9
11. Pigs	0	69	57	0	126
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0
Ferrets	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/23/04

APHIS FORM 7023 (OCT 88), which is obsolete.)
(AUG 91)

Registration #23-R-0033

The IACUC has approved protocols that require multiple survival surgeries:

Procedure for monitoring these activities:
All multiple major survival surgery protocols in large animals are monitored by the Veterinary Technicians who ensure that all records on these animals are maintained in the Laboratory Animal Facility (LAF). These individuals check on all of the animals every day in the LAF. For the mouse protocols the monitoring of these animals is by the investigators and their teams. All LAF staff monitor animals during the course of their daily activities and any animals in need of care are brought to the attention of the Attending Veterinarian and/or the Veterinary Technicians. Monitoring plans are developed on a protocol by protocol basis.

Protocols approved for multiple survival surgeries:

a) A protocol is approved to evaluate the effects of correction of partial bladder obstruction in rabbits (03-289). In the first surgery, a suture is placed around the urethra while a catheter is in place. Between two and ten weeks later, a second midline incision is performed and the suture that restricts the urethra is removed and a small biopsy of the bladder is performed. Animals are then monitored for voiding patterns and/or sacrificed for analyses of molecular correlates of recovery.
b) A protocol is approved to study thymic T cell development in the context of different MHC haplotypes using mice (01-362). In this study, the thymus is removed during the first surgical procedure. Two weeks later the animal undergoes a second surgery to receive the thymus from a different haplotype.
c) A protocol is approved to study voiding patterns in normal mice and in a mouse deleted of SERCA (a gene implicated in bladder obstruction responsiveness) after partial bladder obstruction (02-408). In the first surgery, a suture is placed around the urethra while a small needle is in place. Two to four weeks later, the abdomen is opened again and a small piece of polyethylene tubing is placed into the dome of the bladder. After closure of the surgical site, the bladder and abdominal catheters are attached to pressure transducers to evaluate bladder function in the awake animal. The animal is then euthanized after no longer than 60 minutes, and tissues are harvested for molecular analyses.
d) A protocol to develop an animal model of spina bifida and evaluate strategies for in utero correction is approved in sheep (01-414). At 75 days gestation, a surgical procedure is performed to create the myelomeningocoele defect (spina bifida). At 100 days gestation, a second surgical procedure is performed to correct the defect in some of the animals. At 135-138 days gestation, the animals are delivered by caesarean section. After up to three days, the lambs are euthanized and tissues are harvested for evaluation.
e) A protocol is approved to determine if growth factor expression from an adenoviral vector facilitates wound healing and prevents scar formation (02-451). In this protocol, a small (2 x 2 mm) wound to the cricoid is performed in an adult rabbit. Two weeks later the incision is reopened and an adenoviral vector that should expresses TGFß3 applied to the wound site. After up to three weeks, the animal is euthanized for analysis of healing and transgene expression.

f) A protocol is approved to repeatedly harvest oocytes from xenopus (03-470). The investigator is approved to remove oocytes up to five total times from xenopus with at least one month wait between each surgical procedure.

g) A protocol is approved to study techniques to determine if it is possible to maintain/lengthen blood vessels in culture and then implant them back into the same pig to determine if the vessels are viable (03-490). In the first surgery a segment of the carotid artery is replaced with a segment of the saphenous vein. After maintaining the carotid artery in culture for nine days, it is replaced back into the animal. The patency of the vessel is assessed using a Doppler flow probe two weeks later, and then the animal is euthanized in a terminal surgical procedure after one month to harvest and evaluate the grafts.

h) A protocol is approved to simulate cyanosis and then study the effects of deep hypothermic circulatory arrest in a pig model (02-583). In the first surgery a side-to-side anastomosis is created through a 3-4cm lateral incision through the chest to manifest a SaO2 of 75-85%. Seven days later, the animal undergoes deep hypothermic (18 C) circulatory arrest after bypass for 90 minutes. After re-warming, the animal is allowed to recover. Seven days later the animal is euthanized in a terminal anesthetic procedure and the brains are harvested for analyses.

i) A protocol is approved to create a left-sided diaphragmatic hernia in fetal sheep at approximately 65 days of gestation and determine if tracheal occlusion combined with maternal administration of glucocorticoids can be used to correct the defect (02-616). At approximately 110 days of gestation, the trachea on the same animal is occluded. At 138-140 days of gestation, the lambs are partially delivered by C-section. After a series of blood flow and pulmonary function tests lasting approximately two hours, the lamb is euthanized.

j) A protocol is approved to test the efficacy of anti-tumor drugs in mice by replacing mini osmotic pumps once or possibly twice (03-643). In the first surgery, the pump is placed either subcutaneously or intraperitoneally depending on the bioavailability of the drug. In a subgroup of animals, the pumps are replaced at two weeks. They are also approved to perform a second replacement of the pumps two weeks later.

k) A protocol is approved to study the effects of tracheal occlusion for the treatment of the effects of diaphragmatic hernia using a fetal sheep model (03-652). At approximately 65 days of gestation, a left-sided diaphragmatic hernia is created. At approximately 110 days of gestation, a tracheal occlusion is performed and at 130 days gestation the tracheal occlusion is released. At approximately 138-140 days gestation, the lambs are partially delivered. A series of tests of fluid absorption are made and within three hours the lambs and the ewes are euthanized.

l) A protocol is approved to study pulmonary hypertension observed in a sheep model of congenital diaphragmatic hernia (03-653). At approximately 65 days of gestation, a left-sided diaphragmatic hernia is created. At approximately 139 days of gestation, the lamb is delivered by C-section and the ewe with any unmanipulated lambs are euthanized. The lamb with the surgically introduced diaphragmatic hernia is kept continuously sedated and the responsiveness of the pulmonary system to pharmacologic agents is evaluated. (This is reported as multiple survival surgeries because the fetus undergoes two manipulations).

m) A protocol is approved to study the impact of corticotrophin releasing factor (CRF) system on bladder function in rats with partial bladder obstruction (04-684). In the first surgical procedure, a suture is placed around the urethra with a needle in place. At various times after the obstruction (1, 2, or 6 weeks), catheters are implanted to monitor bladder function and in some cases to administer (CRF) agonists or antagonists intrathecally. The animal is allowed to recover and bladder function is monitored in animals that receive the CRF agents.

The IACUC has approved two exceptions on animal space provisions:

1. The size of cages for sheep is slightly less (18 sq. ft.) than the size identified in the Guide (20 sq. ft.). This decision was based on the recommendation of the Attending Veterinarian and the LAF Manager. These individuals had polled other institutions who indicated that, in their experience, sheep are able to stand, turn around, and lie down in this size cage. The cage size was adopted by the IACUC at its' May 12, 1997 meeting. Since we adopted the use of this size cage, we have observed no evidence of unusual or abnormal behaviors associated with this cage.

2. A subcommittee of the IACUC met on December 2, 2002 to observe swine that were larger than 100 kg, but smaller than 200 kg in weight. These animals were being housed in 24 sq. ft. of space. The Guide calls for 24 sq. ft. for 100 kg swine and 48 sq. ft. for up to 200 kg swine. The subcommittee recommended that swine up to 200 kg in weight could be housed in 24 sq. ft. because they were able to stand around and lie down in apparent comfort. The cage size was adopted by the IACUC at its' December 9, 2002 meeting. Since we adopted the use of this size cage, we have observed no evidence of unusual or abnormal behaviors associated with this cage.

Food or Fluid Restriction

Experimental situations that require food and/or fluid restriction:

Title of Experiment	Justification	Species	Length of Restriction
1. Functional Outcomes of Myelomeningocoele Repairs in Utero (01-414) 2. Cardiac Valvuloplasty in Fetal Sheep (02-604) 3. Tracheal Occlusion for Diaphragmatic Hernia (02-616) 4. Lung Liquid Reabsorption Following Prenatal Tracheal Occlusion (03-652) 5. Manipulation of Pulmonary Vascular Resistance in Congenital Diaphragmatic Hernia (03-653) 6. Fetal Cardiac Therapy (04-697)	Prevention of vomiting and aspiration of stomach contents during anesthetic induction of pregnant sheep.	Sheep	Food withheld for 48 hours prior to surgery with unrestricted access to water.

Variables that are monitored to ensure animal health during the restricted period.
When sheep are fasted for 48 hours, a form is placed on the cage where urine/fecal output is noted daily. If a decrease in fecal or urine output is noted, a Veterinary Technician is notified.

Steps taken to ensure adequate nutrition/hydration during the restricted period.
The sheep are allowed free access to water at all times. We have not observed detrimental effects in the sheep from food restriction, and have a low rate of complications with survival sheep fetal surgeries.

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 21!

See attached form for additional information.

Interagency Report Control #

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 23-R-0068
CUSTOMER NUMBER: 344

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Saint Vincent College
300 Fraser Purchase Rd.
Latrobe, PA 15650

NOV 0 1 2004

Telephone: (724) -539-9761

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

Life Science Research Lab

FACILITY LOCATIONS (Sites) - See Atached Listing

Saint Vincent College

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-humar Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
squirrels		8			8
rats	59	114			114
mice	32	2			2

ASSURANCE STATEMENTS see attached (3 pages)

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual res 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 ap 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 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 INSTITUTION OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/27/0

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

result in an order to cease and desist and to be subject to penalties as provided for in Section

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

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 this form.)*

A. Animals Covered By The Animal Welfare Regulations 12. &/OR 13. Other *(List by species)*	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)

ASSURANCE STATEMENTS see attached

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		10/27/04

7023A
)

PART 1 - HEADQUARTEF

Saint Vincent College 23-R-0068

ANIMAL EUTHANASIA POLICY

If an animal must be euthanized, it is imperative that it be done humanely. Following are three techniques approved by the SVC Institutional Animal Care and Use Committee. The techniques are based on the Report of the American Veterinary Medical Association on Euthanasia (2000). Should circumstances require an alternative euthanasia method, advanced approval must be obtained from the Committee.

A. Asphyxiation with Carbon Dioxide

This technique may be used for mice, rats and guinea pigs.

1. Connect the asphyxiation chamber to the carbon dioxide tank. Place the inlet at the bottom of the chamber and the outlet at the top.

2. Place the lid on the chamber and run the gas for 2-3 minutes so the chamber atmosphere is nearly pure carbon dioxide (60% is the required minimum).

3. Gently lift the lid and lower the animal into the chamber. It is important that the chamber atmosphere be minimally disturbed. Replace the lid.

4. Respiration should cease within 45 seconds. Leave the animal in the chamber for 2-3 minutes after breathing has ceased.

5. Remove the animal from the chamber and turn off the carbon dioxide. Clean the chamber

B. Barbiturate Overdose

This technique may be used for mice, rats and guinea pigs. Barbiturates are controlled substances available only from _____ The drug will be dispensed after all calculations have been checked and actual needs assessed. Students may euthanize animals by barbiturate overdose only in the immediate supervision of

1. Prepare a solution of sodium pentobarbital in 0.9% sodium chloride. The concentration of this solution should be determined using the following guidelines:

   a. Total volume to be injected should be between 0.75 and 1.25 ml per 150g body weight.

   b. Euthanizing (ip.) doses for:

      Mouse: 300 mg/kg
      Rat: 200 mg/kg

Guinea Pig: 100 mg/kg

c. Note that sodium pentobarbital is not completely soluble in aqueous media at the concentrations you will be preparing. Therefore, expect the solutions to be slurries.

2. Administer the appropriate dose intraperitoneally. Since the stock solution is a slurry, be sure to thoroughly mix it immediately before drawing into the syringe.

3. Return the animal to its cage and wait until breathing ceases. This typically requires only a few minutes.

C. Cervical Dislocation

This technique is only for immature rats (weanlings or younger) and mice. Do not attempt this technique without supervision.

1. Lightly anaesthetize the animal with Isoflurane.

2. Place the animal on a hard surface, belly down.

3. Hold the base of the tail with one hand. Place the thumb and index finger of your other hand on either side of the neck at the base of the skull.

3. Quickly pull the base of the tail such that the cervical vertebrae dislocate. Immediately check that the animal has ceased breathing.

Following euthanasia, the carcass is to be tightly sealed in a plastic bag, and placed in the carcass freezer in the LSRL. The log taped to the top of the freezer is to be completed.

Saint Vincent College –23-R-0068

ASSURANCE STATEMENT

Saint Vincent College follows professionally accepted standards regarding the care, treatment and use of animals. Specifically, we comply with Animal Welfare Act (and amendments), we follow the guidelines put forth in the "Guide for the Care and Use of Laboratory Animals" (published by the Animal Resources Program, NIH), and we follow the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association.

All research involving the use of animals is approved by the IACUC. When appropriate, the IACUC directs principal investigators to employ specific alternatives or modifications that reduce the use, pain or suffering of animals. We approve projects that are exceptions to the standards or regulations referred to above only after careful consideration of the scientific and ethical issues involved.

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 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 23-R-0126
CUSTOMER NUMBER: 371

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Summit Ridge Biosystems, Inc.
Summit Ridge Farms
Rd 1 - Box 131
Susquehanna, PA 18847

NOV 2 3 2004

Telephone: (570) -756-2656

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

only as above under headquarters FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		1154	65		1219
5. Cats		473	2		475
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/19/04

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

ADDENDUM TO THE ANNUAL REPORT OF RESEARCH FACILITY

November 19, 2004

Assurance statements:

Below is a summary of all such exemptions to the standards and regulations of the Animal Welfare Act.

From October 1, 2003 to September 30, 2004, the following exemptions were approved by Summit Ridge Farms' Institutional and Animal Care and Use Committee:

Section 3.6 Primary Enclosures

(b) Additional requirements for cats

(3) Litter

A litter exemption was approved 746 times for adult felines participating on stool quality, digestibility, and urine pH trials. The litter exemption was granted to eliminate the possibility of contamination of specimens in studies involving the collection of feces and/or urine.

Section 3.9 Feeding

(a) Diets must be uncontaminated, wholesome, palatable, and of sufficient quantity and nutritive value to maintain the normal condition and weight of the animal.

An exemption to allow test diets for gestation/lactation studies and maintenance studies to be fed longer than six months past the milling date. The purpose of these studies is to prove the nutritional adequacy of the test diet on gestation and lactation or maintenance based on AAFCO feeding protocols. The exemption was approved 441 times for canines on gestation, lactation, and growth studies, 112 times for canines on maintenance studies, 80 times for canines on customized studies, and 24 times for felines on maintenance studies. This equals 633 times total for canines and 24 times total for felines.

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 2150.

See reverse side for additional information

Interagency Report Control No 0130-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 23-R-0126 CUSTOMER NO. 371

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

SUMMIT RIDGE BIOSYSTEMS, INC.
RD 1 - BOX 131
SUSQUEHANNA, PA 18847
(717) 756-2656

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.) only at above under head quarters

FACILITY LOCATIONS *(sites)*

See Attached Listing

11-28-2001 RCVD

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		1132	80		1212
5. Cats		320	22		342
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.

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 INSTI OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/27/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 21!

NOV 2 3 2004

See attached form for additional information.

Interagency Report Contro

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 31-R-0018
CUSTOMER NUMBER: 211

FORM APPROVED
OMB NO. 0579-0036

Iams Company, The
Paul F. Iams Technical Center
7250 Poe Avenue
Dayton, OH 45414

Telephone: (937) -415-8823

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

PHNC 6571 St. RT 503 N Lewisburg FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	10	113	0	0	113
5. Cats	10	197	0	0	197
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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)

SI(	INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
			11/17/0

APHIS FOI
(AUG

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

Iams Pet Health and Nutrition Center

Exception Summary

Cage Requirements

The canine metabolism protocol requires dogs to be temporarily housed in specially designed cages for the collection of urine and feces. Only one size cage is available and it provides nine square feet of floor space. This is adequate floor space for dogs thirty inches or less as measured from the tip of its nose to the base of the tail. The IACUC approved the temporary housing of dogs from thirty-one to forty-five inches for metabolism studies. Dogs within this range of length can comfortably stand, sit, turn-around and lie down, as well as urinate and defecate in a normal posture. Dogs above forty-five inches in length were not approved for use in the canine metabolism protocol.

This report is required by law (? USC 21 43) 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 2150

Set reverse side for additional information

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 31-R-0021
CUSTOMER NUMBER: 228

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA Include Zip Code)

Battelle Memorial Institute
505 King Avenue
Columbus, OH 43201
Telephone: (614) 424-7444

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)

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 those 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		175	152		327
5. Cats					
6. Guinea Pigs	114	1,826	1,083	1,744	4,653
7. Hamsters		73		290	363
8. Rabbits	110	1,039	1,057	418	2,514
9. Non-human Primates	37	308	81	83	472
10. Sheep					
11., Pigs	5	1	27		28
12. Other Farm Animals					
Goat		18			18
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

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 CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-24-03

APHIS FORM 7023
(AUG 91)

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

Customer ID and Site Address:

ID: 228

Medical Research And
Evaluation Facility
State Route 142
JM-1 and JM-3
West Jefferson, OH 43162
County: Madison

Telephone

Customer ID and Site Address:

ID: 228

505 King Avenue
Columbus, OH 43201
County: Franklin

Telephone

Summary of Exceptions to the Regulations or Standards

A. Sanitization of Primary Enclosures

1. A two-day delay was granted to the cage change requirement.
2. This delay was granted due to detectable isotope levels.
3. Species: Primate
4. Number of animals: 5

B. Primary Enclosures

1. Three animals were socially housed instead of pairing to provide social housing for an odd numbered group.
2. This social housing was done to promote species-typical behavior and enhance acclimation.
3. Species: Primate
4. Number of animals: 6

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in these studies: 240

3. Species (common name) of animals used in this study: Rabbit

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

   Aerosol challenge. The challenge was performed using a muzzle-only exposure chamber. The animals were gently hand-held for the dosing. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 63

3. Species (common name) of animals used in this study: Rabbit

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

   Subcutaneous challenge. The dosing procedure involved a subcutaneous injection which did not cause more than momentary pain or distress. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics, and sedatives could not be provided because it has the potential to mask or potentiate the effects of infection and confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians and animal technicians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which are found to be moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 87

3. Species (common name) of animals used in this study: Rabbit

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

   Intramuscular injection. The dosing procedure involved an injection which did not cause more than momentary pain or distress. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 929

3. Species (common name) of animals used in this study: Guinea Pig

   Explain the procedure producing pain and/or distress:

4. Intramuscular and intradermal injection. The dosing procedure involved an injection which did not cause more than momentary pain or distress. The resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund

were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 313

3. Species (common name) of animals used in this study: Guinea Pig

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

   Intraperitoneal challenge of toxins. The dosing procedure involved an injection which did not cause more than momentary pain or distress.

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.

   Anesthetics cannot be used to alleviate distress as they also act as respiratory depressants that could potentiate the toxic action of the test agent. Opioid analgesics and barbiturate sedative-hypnotics both can cause respiratory depression. Benzodiazepines have fewer effects on respiration but have been shown to have substantial respiratory interactions when used in combination with neuroleptic agents. Because of these side effects, anesthetics, analgesics and sedatives could potentiate the toxicological effects of these toxins. As it is difficult to judge the amount of pain or distress involved with toxicity in animals, it is assumed that pain and /or stress are present. The Study Director has consulted with the Study Veterinarian in the planning of all procedures involving unalleviated pain.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 290

3. Species (common name) of animals used in this study: Hamster

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

   Subcutaneous challenge. The dosing procedure involved a subcutaneous injection which did not cause more than momentary pain or distress. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 28

3. Species (common name) of animals used in this study: Rabbit

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

   Subcutaneous challenge. The dosing procedure involved a subcutaneous injection which did not cause more than momentary pain or distress. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 18

3. Species (common name) of animals used in this study: Cynomolgus macaque

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

   Aerosol challenge. The challenge was performed under Telazol® anesthesia using a head-only exposure chamber. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: 21 Part 58

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 3

3. Species (common name) of animals used in this study: Rhesus macaques

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

   Aerosol challenge. The challenge was performed under Telazol® anesthesia using a head-only exposure chamber. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics, and sedatives could not be provided because it had the potential to mask or potentiate the effects of infection and confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians and animal technicians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which are found to be moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 502

3. Species (common name) of animals used in this study: Guinea Pig

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

Intradermal injection. The dosing procedure involved an injection which did not cause more than momentary pain or distress. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 13

3. Species (common name) of animals used in this study: Rhesus macaques

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

   Aerosol challenge. The challenge was performed under Telazol® anesthesia using a head-only exposure chamber. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics, and sedatives could not be provided because it had the potential to mask or potentiate the effects of infection and confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians and animal technicians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which are found to be moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 28

3. Species (common name) of animals used in this study: Cynomolgus macaque

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

   The threat posed by highly toxic compounds and the efficacy of therapy for potential agents was to be evaluated in cynomolgus macaques. Compounds were injected intramuscularly.

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.

   To estimate the toxicity in man and to determine the efficacy of current therapy, it is necessary to use a species of animal known to respond to such agents and therapy in a manner similar to that of man. Toxicity may be due to local effects or to central nervous system effects. The use of any compound that alters function or perception in the central nervous system could increase or decrease the morbidity or mortality and dramatically affect the results of this experiment. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Animals that were moribund were euthanized to relieve pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 5

3. Species (common name) of animals used in this study: Rhesus macaque

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

   To estimate physiological effects in human beings, rhesus monkeys were dosed intramuscularly to determine physiological effects of two unidentified compounds.

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.

   To estimate the physiological effects in man of unidentified compounds and to determine the efficacy of therapy, it is necessary to use a species of animal known to respond to compounds and therapy in a manner similar to that of man. No mortality resulted, but clinical signs were observed. Anesthetics, analgesics and tranquilizers would have interfered with the physiological effects of these compounds. Diazepam was used in two animals after compound injection to determine its effect. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. These data are critical to human safety in the event of exposure.

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:

   Agency: NA CFR: NA

NOV 2 6 2004

This report is required by law (? USC 21 43) 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 2150

Set reverse side for additionalinformation

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 31-R-0021
CUSTOMER NUMBER: 228

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA Include Zip Code)

Battelle Memorial Institute
505 King Avenue
Columbus, OH 43201
Telephone: (614) 424-7444

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)

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 those 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		772	56		828
5. Cats		37			37
6. Guinea Pigs		502	396	397	1,295
7. Hamsters					
8. Rabbits	19	516	1,245	255	2,016
9. Non-human Primates		392	187	97	676
10. Sheep					
11., Pigs			5		5
12. Other Farm Animals					
Goat		28			28
13 Other Animals					
Ferret			34		34

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 veterinarianfor 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 CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-23-04

APHIS FORM 7023
(AUG 91)

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

Customer ID and Site Address:

ID: 228

Medical Research And Evaluation Facility
West Jefferson, OH 43162

Customer ID and Site Address:

ID: 228

Laboratory Animal Resources
Columbus, OH 43201

Summary of Exceptions to the Regulations or Standards

A. Sanitization of Primary Enclosures

(1) 1. A four day delay was granted to the cage change requirement. The cages were cleaned twice daily as per standard procedure.

2. This delay was granted due to animal transfer to new room to minimize additional animal handling.

3. Species: Primate

4. Number of animals: 29

(2) 1. A one day delay was granted to the cage change requirement. The cages were cleaned twice daily as per standard procedure.

2. This delay was granted due to animal transfer to new room to minimize additional animal handling.

3. Species: Dog

4. Number of animals: 12

(3) 1. A one day delay was granted to the cage change requirement. The cages were cleaned twice daily as per standard procedure.

2. This delay was granted due to radiotelemetry data collection in close proximity.

3. Species: Primate

4. Number of animals: 28

B. Primary Enclosures

1. Three animals were socially housed instead of pairing to provide social housing for an odd numbered group.

2. This social housing was done to promote species-typical behavior and enhance acclimation.

3. Species: Primate

4. Number of animals: 6

C. Dog Exercise

1. Exceptions were granted to the dog exercise plan.

2. These exceptions were granted for scientific reasons.

   a. Telemetry Studies

      The dogs had been instrumented with telemetry transmitters for the cardiovascular data collection. Data could only be collected while animals resided in their home cages. Exercise activity would have interfered with data collection and would have confounded data analysis. This baseline and study monitoring occurred while the animals had unrestricted activity within their home cages. These exemptions were of short duration (typically 2 to 3 weeks).

3. Species: Dog

4. Number of animals used: 38

D. Second Major Operative Procedure

1. Two cynomolgus monkeys underwent a second major operative procedure to remove previously implanted radiotelemetry transmitters. This procedure was IACUC approved and USDA approved.

2. The second operative procedure to remove the radiotransmitter allowed for the monkeys to be donated to a breeding facility. In addition, removal of the transmitters avoided long-term medical complications that may occur with implanted foreign material.

3. Species: Primate (cynomolgus)

4. Number of animals: 2

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in these studies: 255

3. Species (common name) of animals used in this study: Rabbit

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

   Aerosol challenge. The challenge was performed using a muzzle-only exposure chamber. The animals were gently hand-held for the dosing. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: FDA

   CFR: As appropriate, study conducted under Title 21, Food and Drugs, specifically, **21CFR.314.610,** approval based on evidence of effectiveness from studies in animals (under subpart I--approval of new drugs when human efficacy studies are not ethical or feasible), and **21CFR601.91,** approval based on evidence of effectiveness from studies in animals (under subpart H--approval of biological products when human efficacy studies are not ethical or feasible).

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 221

3. Species (common name) of animals used in this study: Guinea Pig

   Explain the procedure producing pain and/or distress:

4. Intramuscular and intradermal injection. The dosing procedure involved an injection which did not cause more than momentary pain or distress. The resultant infection may cause pain and/or distress.

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.

Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: FDA

   CFR As appropriate, study conducted under Title 21, Food and Drugs, specifically, **21CFR.314.610,** approval based on evidence of effectiveness from studies in animals (under subpart I--approval of new drugs when human efficacy studies are not ethical or feasible), and **21CFR601.91,** approval based on evidence of effectiveness from studies in animals (under subpart H--approval of biological products when human efficacy studies are not ethical or feasible).

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 10

3. Species (common name) of animals used in this study: Guinea Pig

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

   Intramuscular challenge of toxins. The dosing procedure involved an injection which did not cause more than momentary pain or distress.

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.

   Anesthetics, analgesics and sedatives may potentate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 108

3. Species (common name) of animals used in this study: Guinea Pig

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

   Subcutaneous injection. The dosing procedure involved an injection which did not cause more than momentary pain or distress. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: FDA

   CFR: As appropriate, study conducted under Title 21, Food and Drugs, specifically, **21CFR.314.610,** approval based on evidence of effectiveness from studies in animals (under subpart I--approval of new drugs when human efficacy studies are not ethical or feasible), and **21CFR601.91,** approval based on evidence of effectiveness from studies in animals (under subpart H--approval of biological products when human efficacy studies are not ethical or feasible).

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 58

3. Species (common name) of animals used in this study: Guinea Pig

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

   To estimate physiological effects in human beings, guinea pigs were exposed to aerosols, or contaminated surfaces, or injected subcutaneously to determine physiological effects of unidentified compounds.

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.

   To estimate the physiological effects in man, guinea pigs were exposed to unidentified compounds. It is necessary to use a species of animal known to respond to compounds in a manner similar to that of man. Anesthetics, analgesics and tranquilizers would have interfered with the physiological effects of these compounds. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. These data are critical to human safety in the event of exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 32

3. Species (common name) of animals used in this study: Rhesus macaques

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

   Aerosol challenge. The challenge was performed under Telazol® anesthesia using a head-only exposure chamber. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics, and sedatives could not be provided because it had the potential to mask or potentiate the effects of infection and confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians and animal technicians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which are found to be moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: FDA

   CFR: As appropriate, study conducted under Title 21, Food and Drugs, specifically, **21CFR.314.610,** approval based on evidence of effectiveness from studies in animals (under subpart I--approval of new drugs when human efficacy studies are not ethical or feasible), and **21CFR601.91,** approval based on evidence of effectiveness from studies in animals (under subpart H--approval of biological products when human efficacy studies are not ethical or feasible).

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 10

3. Species (common name) of animals used in this study: Cynomolgus macaques

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

   Aerosol challenge. The challenge was performed under Telazol® anesthesia using a head-only exposure chamber. The dosing procedure itself is not painful but resultant infection may cause pain and/or distress.

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.

   Anesthetics, analgesics, and sedatives could not be provided because it had the potential to mask or potentiate the effects of infection and confound results. There are no known characterized, surrogate markers to predict

mortality. Experienced staff veterinarians and animal technicians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which are found to be moribund were euthanized to alleviate pain and distress. This data is critical to human safety in the event of human exposure.

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:

   Agency: FDA

   CFR: As appropriate, study conducted under Title 21, Food and Drugs, specifically, **21CFR.314.610,** approval based on evidence of effectiveness from studies in animals (under subpart I--approval of new drugs when human efficacy studies are not ethical or feasible), and **21CFR601.91,** approval based on evidence of effectiveness from studies in animals (under subpart H--approval of biological products when human efficacy studies are not ethical or feasible).

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 2

3. Species (common name) of animals used in this study: Cynomolgus macaque

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

   A prophylactic for organophosphorus compound intoxication was evaluated. Compounds were injected intramuscularly.

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.

   To determine the efficacy of a proposed prophylactic, it is necessary to use a species of animal known to respond to toxic agents and therapy in a manner similar to that of man. Toxicity may be due to local effects or to central nervous system effects. The use of any compound that alters function or perception in the central nervous system could increase or decrease the morbidity or mortality and dramatically affect the results of this experiment. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Animals that were moribund were euthanized to relieve pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 50

3. Species (common name) of animals used in this study: Cynomolgus macaque

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

   The threat posed by highly toxic compounds and the efficacy of therapy for potential agents was to be evaluated. Compounds were injected intramuscularly.

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.

   To estimate the toxicity in man and to determine the efficacy of current therapy, it is necessary to use a species of animal known to respond to such agents and therapy in a manner similar to that of man. Toxicity may be due to local effects or to central nervous system effects. The use of any compound that alters function or perception in the central nervous system could increase or decrease the morbidity or mortality and dramatically affect the results of this experiment. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Animals that were moribund were euthanized to relieve pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 3

3. Species (common name) of animals used in this study: Rhesus macaque

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

   To estimate physiological effects in human beings, rhesus monkeys were dosed intramuscularly to determine physiological effects of two unidentified compounds.

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.

   To estimate the physiological effects in man of unidentified compounds and to determine the efficacy of therapy, it is necessary to use a species of animal known to respond to compounds and therapy in a manner similar to that of man. No mortality resulted, but clinical signs were observed. Anesthetics, analgesics and tranquilizers would have interfered with the physiological effects of these compounds. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. These data are critical to human safety in the event of exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 221

3. Species (common name) of animals used in this study: Guinea Pig

4. Explain the procedure producing pain and/or distress: Intramuscular and intradermal injection. The dosing procedure involved an injection with bacterial spores which did not cause more than momentary pain or distress. The resultant bacterial infection may cause pain and/or distress.

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: FDA

   CFR: As appropriate, study conducted under Title 21, Food and Drugs, specifically, **21CFR.314.610,** approval based on evidence of effectiveness from studies in animals (under subpart I--approval of new drugs when human efficacy studies are not ethical or feasible), and **21CFR601.91,** approval based on evidence of effectiveness from studies in animals (under subpart H--approval of biological products when human efficacy studies are not ethical or feasible).

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 10

3. Species (common name) of animals used in this study: Guinea Pig

4. Explain the procedure producing pain and/or distress: Intramuscular challenge of toxins. The dosing procedure involved an injection of a bacterial toxin solution which did not cause more than momentary pain or distress. The resultant toxicity may cause pain and/or distress.

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.

   Anesthetics, analgesics and sedatives may potentate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals

exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 108

3. Species (common name) of animals used in this study: Guinea Pig

4. Explain the procedure producing pain and/or distress: Intramuscular and intradermal injection. The dosing procedure involved an injection with bacterial spores which did not cause more than momentary pain or distress. The resultant bacterial infection may cause pain and/or distress.

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.

   Anesthetics, analgesics and sedatives may potentiate the effects of infection and could confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which were moribund were euthanized to alleviate pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: FDA

   CFR: As appropriate, study conducted under Title 21, Food and Drugs, specifically, **21CFR.314.610,** approval based on evidence of effectiveness from studies in animals (under subpart I--approval of new drugs when human efficacy studies are not ethical or feasible), and **21CFR601.91,** approval based on evidence of effectiveness from studies in animals (under subpart H--approval of biological products when human efficacy studies are not ethical or feasible).

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 32

3. Species (common name) of animals used in this study: Rhesus macaques

4. Explain the procedure producing pain and/or distress: Aerosol challenge with bacterial spores. The challenge was performed under Telazol® anesthesia using a head-only exposure chamber. The challenge procedure itself is not painful but resultant bacterial infection may cause pain and/or distress.

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.

   Anesthetics, analgesics, and sedatives could not be provided because it had the potential to mask or potentiate the effects of infection and confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians and animal technicians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which are found to be moribund were euthanized to alleviate pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: FDA

   CFR: As appropriate, study conducted under Title 21, Food and Drugs, specifically, **21CFR.314.610,** approval based on evidence of effectiveness from studies in animals (under subpart I--approval of new drugs when human efficacy studies are not ethical or feasible), and **21CFR601.91,** approval based on evidence of effectiveness from studies in animals (under subpart H--approval of biological products when human efficacy studies are not ethical or feasible).

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 10

3. Species (common name) of animals used in this study: Cynomolgus macaques

4. Explain the procedure producing pain and/or distress: Aerosol challenge with bacterial spores. The challenge was performed under Telazol® anesthesia using a head-only exposure chamber. The challenge procedure itself is not painful but resultant bacterial infection may cause pain and/or distress.

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.

   Anesthetics, analgesics, and sedatives could not be provided because it had the potential to mask or potentiate the effects of infection and confound results. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians and animal technicians were on site to monitor the study conduct and any animal welfare issues. Pain-relieving drugs are not used, on the basis that death is rapid following the onset of symptoms, and that the use of pain medications could mask the clinical appearance, affecting the experimental data. Animals exhibiting clinical signs or those which are found to be moribund were euthanized to alleviate pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: FDA

   CFR: As appropriate, study conducted under Title 21, Food and Drugs, specifically, **21CFR.314.610,** approval based on evidence of effectiveness from studies in animals (under subpart I--approval of new drugs when human efficacy studies are not ethical or feasible), and **21CFR601.91,** approval based on

evidence of effectiveness from studies in animals (under subpart H--approval of biological products when human efficacy studies are not ethical or feasible).

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 2

3. Species (common name) of animals used in this study: Cynomolgus macaque

4. Explain the procedure producing pain and/or distress: A prophylactic for organophosphorus compound intoxication was evaluated. Compounds were injected intramuscularly. Animals were injected with human butyrylcholinesterase hours prior to injection of an organophosphorus compound to determine efficacy of such treatment in preventing toxicity.

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.

   To determine the efficacy of a proposed prophylactic, it is necessary to use a species of animal known to respond to toxic agents and therapy in a manner similar to that of man. Toxicity may be due to local effects or to central nervous system effects. The use of any compound that alters function or perception in the central nervous system could increase or decrease the morbidity or mortality and dramatically affect the results of this experiment. There are no known characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Animals that were moribund were euthanized to relieve pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 50

3. Species (common name) of animals used in this study: Cynomolgus macaque

4. Explain the procedure producing pain and/or distress: The threat posed by highly toxic compounds and the efficacy of therapy for potential agents was to be evaluated. Compounds were injected intramuscularly. Various oximes, in conjunction with an antimuscarinic and an anxiolytic, were tested for efficacy in treatment of intoxication with an anticholinesterase compound.

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.

   To estimate the toxicity in man and to determine the efficacy of current therapy, it is necessary to use a species of animal known to respond to such agents and therapy in a manner similar to that of man. Toxicity may be due to local effects or to central nervous system effects. The use of any compound that alters function or perception in the central nervous system could increase or decrease the morbidity or mortality and dramatically affect the results of this experiment. There are no known

characterized, surrogate markers to predict mortality. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. Animals that were moribund were euthanized to relieve pain and distress. These data are critical to human safety in the event of human exposure.

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:

   Agency: NA CFR: NA

Column E Explanation Form

1. Registration Number: 31-R-0021

2. Number of animals used in this study: 3

3. Species (common name) of animals used in this study: Rhesus macaque

4. Explain the procedure producing pain and/or distress: To estimate physiological effects in human beings, rhesus monkeys were dosed intramuscularly to determine physiological effects of two unidentified compounds, one of which is reported to be an emetic.

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.

   To estimate the physiological effects in man of unidentified compounds and to determine the efficacy of therapy, it is necessary to use a species of animal known to respond to compounds and therapy in a manner similar to that of man. No mortality resulted, but clinical signs were observed. Anesthetics, analgesics and tranquilizers would have interfered with the physiological effects of these compounds. Experienced staff veterinarians were on site to monitor the study conduct and any animal welfare issues. These data are critical to human safety in the event of exposure.

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:

   Agency: NA CFR: NA

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **REGISTRATION NO.** 31-R-0026 **CUSTOMER NO.** 232

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*

BOWLING GREEN STATE UNIVERSITY
120 MCFALL CENTER
BOWLING GREEN, OH 43403
(419) 372-7710

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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			43		
8. Rabbits			2		
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Deer Mouse		38			

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/13/01

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 31-R-0026
Customer Number: 232
Facility: BOWLING GREEN STATE UNIVERSITY
120 MCFALL CENTER
BOWLING GREEN, OH 43403
(419) 372-7710

LIFE SCIENCE ANNEX
102 LIFE SCIENCE BLDG.
BOWLING GREEN STATE UNIVERSITY
BOWLING GREEN, OH 43403

BEHAVIORAL NEUROSCIENCE ANIMAL FACILITY
PSYCHOLOGY BLDG.
BOWLING GREEN STATE UNIVERSITY
BOWLING GREEN, OH 43403

ECOLOGY AND ETHOLOGY RESEARCH STATION
MERCER ROAD
BOWLING GREEN STATE UNIVERSITY
BOWLING GREEN, OH 43403

HERPETARIUM
111 LIFE SCIENCE BLDG.
BOWLING GREEN STATE UNIVERSITY
BOWLING GREEN, OH 43403

SENSORY ECOLOGY WET LAB
211 LIFE SCIENCE BLDG.
BOWLING GREEN STATE UNIVERSITY
BOWLING GREEN, OH 43403

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 21

See attached form for additional information.

DEC 01 2004

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 31-R-0030

CUSTOMER NUMBER: 224

FORM APPROVED
OMB NO. 0579-0036

~~Kent State University~~
~~Division Of Research & Grad.~~
~~191 Macc Annex~~
~~Kent, OH 44242~~

~~Telephone: (216) 672-2660~~

KentStateUniversity
Div.ofResearch&Grad.
125 Auditorium
Kent,Ohio 44242
(216)672-2704

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

Cunningham Hall

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters	266		523		523
8. Rabbits	8		8		8
9. Non-human Primates					
10. Sheep					
11. Pigs	0		8		8
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 *(Type or Print)*

DATE SIGNED 1/30/04

KENT STATE
UNIVERSITY

November 30, 2004

United States Department of Agriculture
920 Main Campus Drive
Suite 200
Raleigh, NC 27606-5213

RE: Annual Report, Summary of Exceptions
Certificate Number 31-R-0030

To Whom It May Concern:

Please find the enclosed Annual Report of Research Facility for the Cunningham Hall Animal Facility at Kent State University for the reporting period October 1, 2003 through September 30, 2004.

The protocols listed below have cage changes slightly less frequently than normal due to the nature of the research (changed every 2 weeks). Fresh bedding is put in cages as needed on top of old bedding. Cage changing/cleaning has a dramatic phase-resetting effect on the circadian system.

"Neurologic Regulation of the SCN Circadian Clock"
Species: Syrian Hamsters
# of Animals Affected: Approximately 400 over the course of a year with approximately 20-30 affected at one time

"Neurotransmitter Regulation of Circadian Rhythms"
Species: Syrian Hamsters
# of Animals Affected: Approximately 122 over the course of a year

"Breeding and Evaluation of a Possible Spontaneous Circadian Rhythm Mutation in a Syrian Hamster Population"
Species: Syrian Hamster
# of Animals Affected: Approximately 114 over the course of a year

Sincerely,

Division of Research and Graduate Studies
(330) 672-2851 • Fax: (330) 672-2658
Graduate Program Services
(330) 672-2660 • Fax (330) 672-2658
P.O. Box 5190 • Kent, Ohio 44242-0001 • http://www.kent.edu

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 31-R-0066 **CUSTOMER NO.** 236

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

YOUNGSTOWN STATE UNIVERSITY
ONE UNIVERSITY PLAZA
YOUNGSTOWN, OH 44555
(330) 742-3091

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)*

See Attached Listing

MAIN CAMPUS FACILITIES
ONE UNIVERSITY PLAZA
WARD BEECHER HALL
YOUNGSTOWN, OH 44555

NEOUCOM
DOG HOLDING FACILITY
4209 STATE ROUTE 44
ROOTSTOWN, OH 44272

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	21	21	38	0	59
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.

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
(C cer or Legally Responsible Institutional official)
is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL	AME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/27/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	31-R-0066
Customer Number:	236
Facility:	YOUNGSTOWN STATE UNIVERSITY ONE UNIVERSITY PLAZA YOUNGSTOWN, OH 44555 (330) 742-3091

MAIN CAMPUS FACILITIES
ONE UNIVERSITY PLAZA
WARD BEECHER HALL
YOUNGSTOWN, OH 44555

NEOUCOM
DOG HOLDING FACILITY
4209 STATE ROUTE 44
ROOTSTOWN, OH 44272

IACUC APPROVED EXCEPTION TO THE REGULATIONS:

1. Registration Number: 31-R-0066

2. Identify the IACUC-approved exception to the regulations or standards:

   Prolonged cage changing interval for Circadian Rhythm experiments involving Syrian hamsters

3. Description of the exception:

   Animals in circadian rhythms experiments will be housed in special cages equipped with running wheels to monitor their activity rhythms. Some of these experiments will require that the animals be maintained in continuous darkness. The nature of these experiments may require a longer than normal interval between cage changes.

   Animals housed in wheel running cages in constant darkness will only have one animal per cage, and may go without changing for as long as two weeks. This is because a cage change at certain times of day will cause a shift in the animals' circadian rhythms, compromising the experimental results. Animals in constant darkness will have to have their cages changed at specific times scheduled to avoid interfering in the experiments. With a single hamster housed in these rat-sized cages, no adverse effects to the animals have been observed. Animals will be inspected daily by the PI, by the students conducting the experiments, or by the animal care technician.

   The running wheel cages are clear polycarbonate cages, measuring 40x24x20 cm. The running wheels are 17 cm. In diameter and made of aluminum. The cages are cleaned in the same way as all other cages in the animal care facility.

   The only other exception to the 1-week change period is with pregnant hamsters. Cages with pregnant hamsters will not be change from 2 days prior to 7 days after parturition, since the females are extremely resistant to handling during this time and will become unnecessarily stressed.

4. Species (Common name) of animals used in the study: Syrian hamster (Mesocricetus auratus)

5. Number of animals used: 59

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 21! OCT 1 8 2004 See attached form for additional information. Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 31-R-0091
CUSTOMER NUMBER: 254

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Ricerca Biosciences Llc
7528 Auburn Road
P.O. Box 1000
Concord, OH 44077

Telephone: (440) -357-3300

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this repor	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		681			681
5. Cats		52			52
6. Guinea Pigs		230		80	310
7. Hamsters		-			-
8. Rabbits		86		81	167
9. Non-human Primates		-			-
10. Sheep		-			-
11. Pigs mini pigs		20			20
12. Other Farm Animals		-			-
13. Other Animals					
Non-Regulated Animals					
Rats		6,169			6,169
Mice		11,663			11,663

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 *(Type or Print)*	DATE SIGNED
		10/11/04

which is obsolete.)

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 31-R-0092

2. Number 80 G. pigs, 81 Rabbits of animals used in this study.

3. Species (common name) Guinea pigs, Rabbits of animals used in the study.

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

   Materials, solids, liquids, gases are placed onto skin and into the eye for safety assessment of test material in accordance with EPA and OECD guidelines.

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)

   Federally mandated

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 EPA CFR Title 40 Chap I Sub Chp R OECD Guidelines 404, 40

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 21! NOV 2 2 2004 See attached form for additional information. Interagency Report Control No

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 32-R-0025
CUSTOMER NUMBER: 798

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Indiana University School Of Medicine
1120 S. Drive, Fh-302
Indianapolis, IN 46202

Telephone: (317) -274-8649

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	12	125	78		203
5. Cats					
6. Guinea Pigs					
7. Hamsters		102			102
8. Rabbits		24	43		67
9. Non-human Primates	2		4		4
10. Sheep			74		74
11. Pigs			197		197
12. Other Farm Animals					
13. Other Animals					
Ferrett			32		32

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 OI	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/18/04

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

Facilities:

Laboratory Animal Resource Center
Indianapolis IN 46202
Phone: 317-274-8649

Biotechnology Research and Training Center
Indianapolis IN 46202
Phone: 317-274-8649

Conrad Farm
Camby, IN 46202
Phone: 317-274-8649

Exception report:

1. [redacted] This study is approved for chairing a primate for three days if required for emergency medical treatments. The attending veterinarian would determine the necessity of chairing the monkey for treatments. No such treatments were needed during this reporting period.

2. [redacted] This study is approved for suspending lambs in a padded sling because they will have multiple thransthoracic pressure monitoring lines and mechanical pump control lines which will be critical to performance of the study. g. The sternal and groin incisions will be padded where they contact the sling. After further recovery, when the animal is capable of standing on it's own, it will be moved to an adapted metabolic cage that prevents side to side and front to back movement. The animal will be able to stand or lay down. The pump drive cable and monitoring cannulas will be suspended to allow up and down movement, and the animal will be placed in a jacket to prevent access to the cable and cannulas. Zero animals were used on this study during this reporting period.

3. The Laboratory Animal Resource Center has an "Exercise Exemption for Dogs Used in Radioactive Studies" and "Exercise Exemption for Dogs Housed in Recovery Room Cages". The IU School of Medicine IACUC approved both standard operating procedures. Copies are attached.

Laboratory Animal Resource Center
Indiana University School of Medicine

SOP#: 4025.01 Approved by:
Replaces: 4025.00
Effective Date: January 9, 2002

Exercise Exemption for Dogs and Pigs

When a non-conditioned dog or pig is delivered to the large animal area of LARC it can be housed temporarily in a transport cart even if such cart does not meet the minimum housing requirements. Eight hours is the maximum time an animal will be held in a transport cart, but ultimately a LARC veterinarian can make the decision to have the animal transferred from the transport cart to other temporary housing prior to this eight-hour period. Food and water will be provided as appropriate.

The animal may be transferred to a run in a room housing only non-conditioned animals of the same species or the animal may be put into a mobile recovery cage used for chronic housing, and this cage put into a room that temporarily is used for housing only non-conditioned animals. If the animal is put into a mobile cage then the animal still may be exempt from normal exercise requirements or the animal may be let out of the cage to exercise in the room if appropriate. The PI will be responsible for the extra costs of sanitizing the room that housed the non-conditioned animal.

In the rare instance when the PI cannot use the non-conditioned animal on the date of arrival, and where a housing room is unavailable, then to prevent needless euthanasia the animal will be allowed to stay overnight in the largest available mobile cage, but the PI must take the animal the next day, and again the PI will be responsible for all appropriate charges.

Approved by the I.U. School of Medicine IACUC on the effect date above

Laboratory Animal Resource Center
Indiana University School of Medicine

SOP#: 4010.01 Approved by:
Replaces: 4010.00
Effective Date: March 13, 1997

Exercise Exemption for Dogs Used in Radioactive Studies

In order to decrease the chance for radioactive contamination, dogs injected with radioactive isotopes will not be allowed to participate in the established exercise program. Animals will be restricted to their pens. A dedicated transport cart will be used to hold affected animals during pen washdown.

Approved by the I.U. School of Medicine IACUC	3/97
Reviewed by the I.U. School of Medicine IACUC	6/99

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

585

1. REGISTRATION NO. ~~33-R-0027~~ 33R 0027

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Finch University of Health Science
3333 Green Bay Road
~~AR13A, Dept. 403~~
North Chicago, IL 60064
Status: Active

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)*

~~See Attached~~

NOV 15 1999

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	0	6	0	0	6
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	29	0	29
12. Other Farm Animals	0	0	0	0	0
Mini Pigs	114	90	18	0	108
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.

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
		11/1/99

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 33-R-0029 33R0029

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

603

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

University of Illinois at Urbana-C
1 Observatory Building
901 S. Mathews
Urbana, IL 61801
Status: Active

NOV 29 1999

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)*

See Attached

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	30	86	76		162
5. Cats	10	22	8		30
6. Guinea Pigs	17	8	6		14
7. Hamsters	59	176	93		269
8. Rabbits	98	20	153	37	210
9. Non-human Primates					
10. Sheep			38		38
11. Pigs		210	422	38	670
12. Other Farm Animals					
13. Other Animals					
See 7023A					

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
		11/19

APHIS FORM (AUG 91) (Replaces VS FORM -23 (OCT 88), which is obsolete.)

33R0029

NOV 29 1999

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. **Registration Number**: 33-R-0029

2. **Number** 38 **of animals used in this study.**

3. **Species** (common name) Pigs **of animals used in this study.**

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

   Pigs are inoculated per mouth or intraperitonedly with *Salmonella choleraesuis*. Both procedures are quick and cause no obvious undue stress. No clinical disease is seen before pigs are killed for sample collections, three to five days later.

5. **Provide scientific justification why pain and/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 question 6 below)

   If pain or distress would have been observed in inoculated pigs, (moderate or moderately severe clinical disease), the pigs would have been euthanized. Pain and distress was unlikely when project proposed and data from original pigs confirm it is not a problem.

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_____ **CFR**_____

33R0029

NOV 29 1999

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. **Registration Number**: 33-R-0029

2. **Number** 33 **of animals used in this study.**

3. **Species** (common name) Rabbit **of animals used in this study.**

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

   Rabbits are used for antibody production. They are immunized with substances known as antigens. Inflammation is referred to as swelling at sites of immunization. Swelling at sites of immunization is normal, and in some circumstances can be associated with discomfort or pain, inflammation is transient (5-10 days), then naturally subsides.

5. **Provide scientific justification why pain and/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 question 6 below)

   Because these studies are directed to stimulate inflammation, as part of the immune response, drugs designed to inhibit inflammation may affect the desired outcome-antibody production. In the event that injury or elevated inflammation should occur, veterinary administration of analgesics (or other treatment) is encouraged.

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_____ **CFR**_____

33R 0029

NOV 29 1999

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. **Registration Number**: 33-R-0029

2. **Number** 4 **of animals used in this study.**

3. **Species** (common name) Rabbits **of animals used in this study.**

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

   Rabbits experience minimal pain when blood is taken from the marginal ear vein. Rabbits are placed in a restraining cage, the vein is nicked with a razor blade, and blood collected. After collection of blood, pressure is put on the vein for a few minutes to stop bleeding.

5. **Provide scientific justification why pain and/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 question 6 below)

   There is no need to anesthetize the rabbits because the procedure is gentle and quick. Anesthesia will be more traumatic than nicking the marginal ear vein. We handle our rabbits daily so they are not stressed when removed from their cages and placed in the restraining cage.

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_____ **CFR**_____

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150. additional information

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
33-R-0029

FORM APPROVED
OMB NO. 0579-0036

NOV 29 1999

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

University of Illinois at Urbana-Champaign
1. Observatory Building
901 S. Mathews
Urbana, IL 61801

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12 &/OR 13 Other *(List by species)*	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)
Other Animals:					
Ground Squirrels	11				
Chinchillas	8		42		42
Gerbil	4	60		4	64
Peromyscus	4	31			31
Bats	9		30		30
Ferrets			23		23
Other Farm Animals:					
Goats		1	17		18
Horses		35	29	4	68
Cows		19	24	3	46
Llama		1			1

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
		11/19

APHIS FORM 7023A
(AUG 91)

PART I HEADQUARTERS

33R0029

NOV 29 1999

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. **Registration Number**: 33-R-0029

2. **Number** 4 **of animals used in this study.**

3. **Species** (common name) Gerbil **of animals used in this study.**

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

   Attempted isolation of a protozoan, *Neospora caninum*, in gerbils. Gerbils experience no pain beyond a brief injection, until such time that they may become ill. Once discovered to be ill, they will be euthanized.

5. **Provide scientific justification why pain and/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 question 6 below)

   No significant pain is expected, as gerbils will be promptly euthanized if they become ill. Alleviation of pain is a moot point become ill gerbils will be euthanized.

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_____ **CFR**_____

33R0029

NOV 29 1999

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. **Registration Number**: 33-R-0029

2. **Number** 4 **of animals used in this study.**

3. **Species** (common name) Horse **of animals used in this study.**

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

   Administering a toxin that will induce nervous disease in treated horses. Horses are euthanized when mild signs of nerve damage are present; however, these signs may rapidly progress within hours.

5. **Provide scientific justification why pain and/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 question 6 below)

   The horses need to develop documentable nervous disease in order to permit accurate determination of the cause for the nervous disease. The study is funded by the USDA Cooperative State Research, Education, and Extension Service.

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_____ **CFR**_____

33R0029

NOV 29 1999

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. **Registration Number**: 33-R-0029

2. **Number** 3 **of animals used in this study.**

3. **Species** (common name) Holstein calves **of animals used in this study.**

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

   Neonatal calves are placed in a metabolism cage and inoculated with *Cryptosporidium parvum*. Discomfort occurs due to the presence of diarrhea.

5. **Provide scientific justification why pain and/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 question 6 below)

   The production of large numbers of *C. parvum* oocysts requires the induction of diarrhea. Calves are kept hydrated throughout the study with the use of oral glucose/electrolyte solutions.

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_____ **CFR**_____

33 R0029
NOV 29 1999

33-R-0029

Facility Locations

Department of Psychology
Psychology Building
603 East Daniel
Champaign IL 61820

Contact person:

College of Agricultural, Consumer and Environmental Sciences
Edward R. Madigan Laboratory
1301 W. Gregory Drive
Urbana IL 61801

Contact person:

Agricultural Farms
Swine, Cattle, Horse Sheep Facilities
Urbana IL 61801

Contact person:

College of Veterinary Medicine
Veterinary Medicine Basic Sciences Building
2001 S. Lincoln Avenue
Urbana IL 61802

Contact person:

Veterinary Medicine Teaching Hospital
1008 W. Hazelwood Drive
Urbana IL 61802

Contact person:

College of Veterinary Medicine (Farm)
South Race Street
Urbana IL 61802

Contact person:

School of Life Sciences/College of Medicine
505 S. Goodwin/506 S. Mathews
Urbana IL 61801

Contact person:

Beckman Institute
405 North Mathews
Urbana IL 61801

Contact person:

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 21!

NOV 26 2003

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 33-R-0090
CUSTOMER NUMBER: 573

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Tox Monitor Laboratories, Inc.
33 W. Chicago Avenue
Oak Park, IL 60302

Telephone: (708) -345-6970

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		521			521
7. Hamsters					
8. Rabbits		555	90	88	733
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
RAT	946				

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 (Type or Print)	DATE SIGNED
		11/24/03

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 33-R-0090

2. Number 88 of animals used in this study.

3. Species (common name) Rabbit of animals used in the study.

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

ACUTE DERMAL TOXICITY MAY CAUSE MODERATE DERMAL IRRITATION. THE RECOVERY PERIOD PRESCRIBED BY REGULATORY AGENCIES (EPA) DOES NOT EXCEED 14 DAYS.

SKIN IRRITATION CAN CAUSE LIMITED DERMAL IRRITATION/DISCOMFORT. CORROSIVITY STUDIES CAN CAUSE SOME DERMAL IRRITATION/DISCOMFORT. RECOVERY OBSERVATIONS ARE LIMITED TO 14 DAYS.

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)

SINCE DERMAL LD 50 REQUIRES THAT ALL ANIMALS SURVIVE A 14 DAY POST DOSING INTERVAL THE ANIMALS ARE OBSERVED DAILY FOR 14 DAYS. MORTALITY IS ASSESSED END POINT OF THE PROTOCOL THE DATA IS THEREFORE COLLECTED AND SUBMITTED FOR EPA REVIEW.
PROVISION IS ALWAYS MADE FOR THE ANIMALS' COMFORT + WELL BEING WHILE ON STUDY.

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 EPA / D.O.T / FHSA CFR 16 CFR 1500, 40 CFR 160

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **REGISTRATION NO.** 34-R-0010 **CUSTOMER NO.** 111

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA. include Zip Code)*

HENRY FORD HOSPITAL
2799 W GRAND BLVD
DETROIT, MI 48202
(313) 876-2024

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)*

See Attached Listing

11-23-2001 RCVD

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			125		125
5. Cats			0		0
6. Guinea Pigs			0		0
7. Hamsters			0		0
8. Rabbits			226		226
9. Non-Human Primates			0		0
10. Sheep			0		0
11. Pigs			13		13
12. Other Farm Animals			0		0
13. Other Animals ferrets			22		22

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/20/01

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 34-R-0010 CUSTOMER NO. 111

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA include Zip Code)*

HENRY FORD HOSPITAL
2799 W GRAND BLVD
DETROIT, MI 48202
(313) 876-2024

EXCEPTION TO THE REGULATIONS AND STANDARDS

Six pigs received a special liquid diet in a training project for physicians and nurses. These individuals are taught a new endoscopic procedure (Endoscopic Gastroplication) for treating gastroesophageal reflux disease (GERD). The procedure is a non-operative technique by which the barrier between the stomach and the esophagus is bolstered to prevent stomach contents from refluxing up into the esophagus. Since 10% of the population of the U.S. requires daily therapy for GERD, endoscopic gastroplication is emerging as a viable alternative to medical and surgical therapy of GERD for some patients.

Physicians and nurses need specific training for proficiency and need to learn to work as a team in order to successfully use the device. The pig's esophagus and stomach are well suited as a model to simulate the human anatomy for training purposes.

A liquid diet of Ensure was given to the pigs for 60 hours prior to the procedure, and water only during the 12 hours preceding the procedure. The stomach needs to be empty for adequate visualization of the mucosa during the procedure. The liquid diet allows for more rapid emptying of the stomach than grain or vegetation. Any liquid still present in the stomach at the time of the procedure can be readily aspirated through the endoscope.

The pigs readily consumed the liquid diet and suffered no ill effects.

FACILITY SITES LISTING

Licenses/Registrant Name: Henry Ford Hospital
License/Registration Number: 34-R-0010

Site No.: 1	Name/Department:	Bioresources Department
	Address:	2799 W. Grand Blvd.
		Detroit MI 48202
	Building:	Education and Research Bldg.
	Floor/Room:	4th Floor, Room 4002
	Contact Person:	[redacted] Phone No.:
Location	Name/Department:	Bioresources F1
	Address:	One Ford Place
		Detroit MI 48202
	Building:	One Ford Place
	Floor/Room:	3D
	Contact Person:	[redacted] Phone No.:
Location	Name/Department:	Research Institute, William Beaumont Hospital
	Address:	3601 West Thirteen Mile Road
		Royal Oak MI 48073
	Building:	Research Institute
	Floor:	NA
	Contact Person	[redacted] Phone No:
Location	Name/Department	Wayne State University, DLAR
	Address:	1400 Chrysler Freeway
		Detroit MI 48201
	Building:	Shapiro Hall
	Floor:	Eighth Floor
	Contact Person:	[redacted] Phone No:

PLEASE REMOVE MICHIGAN STATE UNIVERSITY AS A HOUSING SITE.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **REGISTRATION NO.** 34-R-0025 **CUSTOMER NO.** 473

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*

NORTHERN BIOMEDICAL RESEARCH, INC.
930 W. SHERMAN BLVD
MUSKEGON, MI 49441
(231) 759-2333

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)*

See Attached Listing
930 W. Sherman Blvd.
Muskegon, MI 49441

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	32	0	192	0	192
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-Human Primates	41	0	9	0	9
10. Sheep	9	0	91	0	91
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	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, 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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10-30-01

APHIS FORM 7023 (AUG 91)

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

PART 1 - HEADQUARTERS

Animal Report of Research Facility Summary of Exceptions 2000-2001 year
Registration No. 34-R-0025

An exception to the standards and regulations under the Act, involves non-human primate caging during the 2000-2001 year. Wall mounted non-human primate caging was installed in one study room to augment our standard primate housing in 1998. The cages provide approximately 4.2ft^2 of floor space rather than the 4.3 ft^2 required for non-human primates between 3 to 10 kg. Cage height is 34.6 inches. The cages slant outward from the bottom and the total volume is greater that 12.0 ft^3. Height and volume are both above the required 30 inch height and 10.75 ft^3 volume. The guidelines state that innovative primary enclosures not precisely meeting the floor area and height requirements, but that do provide a sufficient volume of space and opportunity to express species typical behavior may be used when approved by the Committee. The cage measurements and a study in which primate behavior (macaques and baboons) was compared between animals housed in caging similar to the ones in question at NBR and those of 4.5 ft^2 floor space were discussed. The study discovered no behavioral evidence that a 4.0 ft^2 variant cage was not a suitable substitute for a 4.5 ft^2 floor area cage. The Animal Care and Use Committee approved the use of the 4.2 ft^2 floor area, 34.6 inch height and > 12.0 ft^2 volume cages for animals in the 3 to 10 kg weight range. Thirty rhesus monkeys were housed in the cages from February 2, 2001 through September 30, 2001.

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 21!

OCT 1 8 2004

See attached form for additional information.

Interagency Report Control

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 34-R-0025
CUSTOMER NUMBER: 473

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Northern Biomedical Research Inc
930 W. Sherman Blvd
Muskegon, MI 49441

Telephone: (231) -759-2333

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

930 W. Sherman Blvd
Muskegon MI 49441

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	4	4	118	0	122
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	16	11	74	0	85
10. Sheep	2	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
				0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (*Type or Print*)	DATE SIGNED
		10-11-04

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

Animal Report of Research Facility Summary of Exceptions 2003-2004
Registration No. 34-R-0025

An exception to the standards and regulations under the Act, involves non-human primate caging during 2003-2004. Wall mounted non-human primate caging was installed in one study room to augment our standard primate housing in 1998. The cages provide approximately 4.2 ft^2 of floor space rather than the 4.3 ft^2 required for non-human primates between 3 to 10 kg. Cage height is 34.6 inches. The cages slant outward from the bottom and the total volume is greater than 12.0 ft^3. Height and volume are both above the required 30 inch height and 10.75 ft^3 volume. The guidelines state that innovative primary enclosures not precisely meeting the floor area and height requirements, but that do provide a sufficient volume of space and opportunity to express species typical behavior may be used when approved by the Committee. The cage measurements and a study in which primate behavior (macaques and baboons) was compared between animals housed in caging similar to the ones in question at NBR and those of 4.5 ft^2 floor space were discussed. The study discovered no behavioral evidence that a 4.0 ft^2 variant cage was not a suitable substitute for a 4.5 ft^2 floor area cage. The Animal Care and Use Committee approved the use of the 4.2 ft^2 floor area, 34.6 inch height and > 12.0 ft^2 volume cages for animals in the 3 to 10 kg weight range. A total of sixty-one rhesus monkeys were housed in these cages at various times during the period of October 1, 2003 through September 30, 2004.

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 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 34-R-0031
CUSTOMER NUMBER: 696

FORM APPROVED
OMB NO. 0579-0036

M P I Research, Inc.
54943 N. Main Street
Mattawan, MI 49071

Telephone: (269) -668-3336

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

FACILITY LOCATIONS (Sites) - See Atached Listing Only one site (see above)

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 ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	65	1,845	245	55	2,145
5. Cats	0	62	0	4	66
6. Guinea Pigs	0	88	94	144	326
7. Hamsters	0	0	0	0	0
8. Rabbits	8	963	251	0	1,214
9. Non-human Primates	228	758	87	2	847
10. Sheep	0	0	0	0	0
11. Pigs	200	46	624	0	670
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/20/0

APHIS FORM 7023 (Replaces VS 18-23 (OCT 88), which is obsolete.)
(AUG 91)

Summary of Exceptions

Registration Number: 34-R-0031

Summary of Exceptions to the Regulations and Standards

- There were no exceptions to the regulations and standards.

Column E Explanation

Registration Number: 34-R-0031

STUDY 1

- Number of Animals: 4
- Species: Dog

- Explanation of Procedure Producing Pain and/or Distress

  An Oral (Gavage) toxicity study resulted in emesis with red material on Day 1. Dosing was continued in these animals with the objective of the dogs developing histological lesions. The animals were closely monitored by technicians and veterinarians and supportive treatment provided until the animals were euthanized.

- Scientific Justification

  The EPA requires this testing

- Regulations

  Direct communication between Sponsor and EPA.

  Environmental Protection Agency FIFRA Good Laboratory Practice Standards, 40 CFR Part 160, Toxic Substance Control Act Good Laboratory Practice Standards, 40 CFR Part 792, and OECD Principles of Good Laboratory Practice ENV/MC/CHEM (98) 17.

Column E Explanation

Registration Number: 34-R-0031

STUDY 2

- Number of Animals: 32
- Species : Dog

- Explanation of Procedure Producing Pain and/or Distress

  The test and control articles were administered by I.V. Infusion. All personnel administering the materials were thoroughly trained to avoid potential injury to the animals. Specifically, animals were closely monitored by technicians and veterinarians for general signs of toxicity, inappetance, and stool. (General clinical findings were considered toxicity findings, and were probably due to toxicity of the vehicle since the controls were also affected).

- Scientific Justification

  The FDA requires this testing.

  The route of administration and the vehicle was considered the most appropriate by the Sponsor to meet the objectives of this safety evaluation study.

- Regulations

  International Conference on Harmoniation (ICH) Harmonized Tripartite Guidelines for Pharmaceuticals, and generally accepted procedures for the testing of pharmaceutical compounds.

Column E Explanation

Registration Number: 34-R-0031

STUDY 3

- Number of Animals: 8
- Species: Dog

- Explanation of Procedure Producing Pain and/or Distress

  An Oral (Capsule dose) toxicity study resulted in marked weight loss. Dosing was continued in these animals with the objective of the dogs developing histological lesions. The animals were closely monitored by technicians and veterinarians and supportive treatment provided until the animals were euthanized.

- Scientific Justification

  The FDA requires this testing

- Regulations

  Direct communication between Sponsor and FDA.

  This study is based on the FDA's Current View on Safety Evaluations of Drugs as well as generally accepted procedures for the testing of pharmaceutical compounds.

  International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines, ICH M3.

Column E Explanation

Registration Number: 34-R-0031

STUDY 4

- Number of Animals: 3
- Species: Dog

- Explanation of Procedure Producing Pain and/or Distress

  An Oral (Capsule dose) toxicity study resulted in marked weight loss. Dosing was continued in these animals with the objective of the dogs developing histological lesions. The animals were closely monitored by technicians and veterinarians and supportive treatment provided until the animals were euthanized.

- Scientific Justification

  The FDA requires this testing

- Regulations

  Direct communication between Sponsor and FDA.

  This study is based on the FDA's Current View on Safety Evaluations of Drugs as well as generally accepted procedures for the testing of pharmaceutical compounds.

  International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines, ICH M3.

Column E Explanation

Registration Number: 34-R-0031

STUDY 5

- Number of Animals: 4
- Species : Cat

- Explanation of Procedure Producing Pain and/or Distress

  The test and control articles were administered by I.V. Infusion. All personnel administering the materials were thoroughly trained to avoid potential injury to the animals. Specifically, animals were closely monitored by technicians and veterinarians for general signs of toxicity. (General clinical findings were considered toxicity findings. Four died at first dose.)

- Scientific Justification

  The FDA Center for Veterinary Medicine (CVM) requires this testing.

  The route of administration was considered the most appropriate by the Sponsor and FDA to meet the objectives of this safety evaluation study.

- Regulations

  FDA Center for Veterinary Medicine (CVM) Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials, Guidance #56 and #85.

Column E Explanation

Registration Number: 34-R-0031

STUDY 6

- Number of Animals: 1
- Species: Monkey

- Explanation of Procedure Producing Pain and/or Distress

  A subcutaneous dose toxicity study resulted in marked debilitation. Dosing was continued with the objective of the animal developing histological lesions. The animals were closely monitored by technicians and veterinarians and supportive treatment provided until the animal was euthanized.

- Scientific Justification

  The FDA requires this testing

- Regulations

  Direct communication between Sponsor and FDA.

  This study is based on the FDA's Current View on Safety Evaluations of Drugs as well as generally accepted procedures for the testing of pharmaceutical compounds.

  International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines, ICH M3.

Column E Explanation

Registration Number: 34-R-0031

STUDY 7

- Number of Animals: 96
- Species : Guinea Pig

- Explanation of Procedure Producing Pain and/or Distress

  Skin sensitization studies were conducted to determine the potential for the test articles to produce allergy in human beings. The Maximization method used requires intradermal injection of Freund's Complete Adjuvant that typically produces localized skin ulcers at the injection site. The animals remained active, alert, and good appetites with no overt signs of pain.

- Scientific Justification

  The nature of these test articles required the use of the Maximization method. The EPA and FDA requires skin sensitization testing.

- Regulations

  FDA Guidelines for Preclinical Toxicity Testing of Investigational Drugs for Human Use as well as generally accepted procedures for the testing of pharmaceutical compounds.

  The United States Environmental Protection Agency (EPA), Office of Prevention, Pesticides and Toxic Substances, OPPTS Series 870-2600, 1998.

  The Organization for Economic Cooperation and Development (OECD). Guideline 406, Skin Sensitization.

Column E Explanation

Registration Number: 34-R-0031

STUDY 8

- Number of Animals: 1
- Species: Monkey

- Explanation of Procedure Producing Pain and/or Distress

  An Oral (Gavage dose) toxicity study resulted in weight loss. Dosing was continued in these animals with the objective of the dogs developing histological lesions. The animal was closely monitored by technicians and veterinarians and supportive treatment provided.

- Scientific Justification

  The FDA requires this testing

- Regulations

  Direct communication between Sponsor and FDA.

  This study is based on the FDA's Current View on Safety Evaluations of Drugs as well as generally accepted procedures for the testing of pharmaceutical compounds.

  International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines, ICH M3.

Column E Explanation

Registration Number: 34-R-0031

STUDY 9

- Number of Animals: 4
- Species : Dog

- Explanation of Procedure Producing Pain and/or Distress

  The test and control articles were administered orally. All personnel administering the materials were thoroughly trained to avoid potential injury to the animals. Specifically, animals were closely monitored by technicians and veterinarians for general signs of toxicity, inappetance, and stool. (General clinical findings were considered toxicity findings. Three dogs were euthanized and one died.)

- Scientific Justification

  The FDA, Center for Veterinary Medicine (CVM) requires this testing.

  The route of administration was considered the most appropriate by the Sponsor and FDA to meet the objectives of this safety evaluation study.

- Regulations

  Target Animal Safety Guidelines for New Animal Drugs, Guideline 33, Center for Veterinary Medicine (CVM), Food and Drug Administration (FDA), 1998.

Column E Explanation

Registration Number: 34-R-0031

STUDY 10

- Number of Animals: 4
- Species : Dog

- Explanation of Procedure Producing Pain and/or Distress

  The test and control articles were administered orally. All personnel administering the materials were thoroughly trained to avoid potential injury to the animals. Specifically, animals were closely monitored by technicians and veterinarians for general signs of toxicity, inappetance, and stool. (General clinical findings were considered toxicity findings).

- Scientific Justification

  The FDA requires this testing.

  The route of administration was considered the most appropriate by the Sponsor and FDA to meet the objectives of this safety evaluation study.

- Regulations

  International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines, and generally accepted procedures for the testing of pharmaceutical compounds.

Column E Explanation

Registration Number: 34-R-0031

STUDY 11

- Number of Animals: 48
- Species : Guinea Pig

- Explanation of Procedure Producing Pain and/or Distress

  Skin sensitization studies were conducted to determine the potential for the test articles to produce allergy in human beings. The Maximization method used requires intradermal injection of Freund's Complete Adjuvant that typically produces localized skin ulcers at the injection site. The animals remained active, alert, and good appetites with no overt signs of pain.

- Scientific Justification

  The nature of these test articles required the use of the Maximization method. The EPA and FDA requires skin sensitization testing.

- Regulations

  The United States Environmental Protection Agency (EPA), Office of Prevention, Pesticides and Toxic Substances, Health Effects Test Guidelines, OPPTS 870.2600.

  The EPA, Toxic Substances Control Act (TSCA), Health Effects Test Guidelines, 798.4100.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

12-03-2001 RCVD

1. REGISTRATION NO. 34-R-0038 **CUSTOMER NO.** 201

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA. include Zip Code)*

OAKLAND UNIVERSITY
OFFICE OF RESEARCH & ACADEMIC DEVELOPMENT
ROCHESTER, MI 48309
(810) 370-3222

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.) Biomedical Research Support Facility

FACILITY LOCATIONS*(sites)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	16	80			80
7. Hamsters					
8. Rabbits	9	14	28		42
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Frog(R.Sylvatica)	-0-	3,812			3,812

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/30/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

Registration #34-R-0038

2000/2001 Annual Report Attachment: Summary of IACUC Exceptions to the AWA

The IACUC approved two exceptions to the Standards and Regulations for the care and use of guinea pigs. The exceptions approved were variances in 1) the minimum interior height requirement of the primary enclosures used to house the animals, and 2) their normal diurnal light cycles.

Twenty-three (23) guinea pigs involved in a study investigating the effects of ultra violet (UV) radiation on cataract formation in the lens were housed in specially modified cages containing two "black light" UV lamps mounted to the inside top of the cage.

This lamp arrangement, along with the need for a 1/4" mesh screen to prevent the animals from coming in direct contact with the lamps or their fixtures, resulted in a minimum height of five inches (5") directly under the lamps (approximately 50% of the cage floor space) and a minimum height of six inches (6") between the lamps.

The animals were exposed to the UV light continuously. Normal room lights were activated only for daily inspection and examination of the animals and to provide proper lighting for daily animal care duties.

The health status of these animals was routinely monitored by the veterinarian, animal care staff and the principal investigator for signs of ill effects from the UV exposure and/or primary housing conditions. No complications resulting from such were encountered.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

OCT 1 2 ...

1. REGISTRATION NO. 34-R-0145 | CUSTOMER NO. 1825

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

ESPERION THERAPEUTICS, INC.
3621 S. STATE STREET
695 KMS PLACE
ANN ARBOR, MI 48108
(734) 677-1559

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)*

See Attached Listing

1) 1180 EAST ELLSWORTH, SUITE V.
ANN ARBOR, MI 48108

2) 695 KMS PLACE, 3621 SOUTH STATE ST.
ANN ARBOR, MI 48108

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			41		41
8. Rabbits		27			27
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/4/01

APHIS FORM (AUG 91)

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

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **REGISTRATION NO.** 35-R-0012 **CUSTOMER NO.** 800

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*

GALA DESIGN INC
P.O. BOX 520
SAUK CITY, WI 53583-0520

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)*

OAK HILL FARMS
HILLPOINT, WI 53937

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 appropnate 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					
cattle	106		11		11
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/19/2001

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 35-R-0012

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

cattle (0)

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

4 animals were subjected to ovariectomy per vaginal incision, 7 animals were subjected to caesarian section delivery of calves. All

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)

Not applicable. Pain and distress were relieved by application of regional anesthesia prior to surgery.

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: CFR:

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 21

278-9

See attached form for additional information.

Interagency Report Control No.: 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 43-R-0048
CUSTOMER NUMBER: 1461

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

University of Missouri, Columbia, MO 65211

University Of Missouri-Columbia
205 Jesse Hall

Columbia, MO 65211

Telephone:
(573)882-9500

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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 NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	50	32	284	0	315
5. Cats	2	23	30	0	53
6. Guinea Pigs	1	131	68	0	199
7. Hamsters	0	192	0	0	192
8. Rabbits	15	39	164	0	203
9. Non-human Primates	0	0	0	0	0
0. Sheep	2	50	158	0	208
1. Pigs	529	799	24	39	862
2. Other Farm Animals cattle	0	444	48	0	492
horses	10	49	15	9	73
3. Other Animals					
bats	8	190	25	0	215
opossum	0	0	5	0	5
wild mice	0	150	0	0	150

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, 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)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
	11/20/00

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 43-R-0048

FORM APPROVED
OMB NO. 0579-0036

University of Missouri, Columbia, MO 65211

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

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

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations 12. &/OR 13. Other *(List by species)*	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)
13: other animals cont.					
gerbils	70	0	270	0	270
voles	0	50	0	0	50

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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).

	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/20/00

APHIS FORM 7023A

University of Missouri-Columbia (43-R-048)

Annual Report of Research Facility - Attachments

FACILITY LOCATIONS:

Allton 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, A266, A268, A273, B120C, B125, B208, B213, & B229

Connaway Hall

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

Dalton Research Center

-animal housing facility: rooms 106, 108, 112, 114, 116, 118, 124, 221A, 225A, 226, 228, 230, 233A, 233B, 311, 312, 313, 329, 331, 334

-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

Lefevre 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

Middlebush Farm

-animal housing and use: Equine Center, Theriogenology Bldg., paddocks

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 21

291-5

See attached form for additional information.

Interagency Report Control No 0180-0OA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 47-R-0010
CUSTOMER NUMBER: 1550

FORM APPROVED
OMB NO. 0579-0036

NOV 29 2000

Schering-Plough Animal Health
Po Box 3113

Omaha, NE 68103

Telephone:
(402)331-3900

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

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7021A)

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 NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	2	163	45	52	260
5. Cats	10	176	27	12	215
6. Guinea Pigs	16	637	102	128	867
7. Hamsters	23	775	0	1205	1980
8. Rabbits	0	47	704	0	751
9. Non-human Primates	0	0	0	0	0
0. Sheep	0	0	0	0	0
1. Pigs	0	0	0	0	0
2. Other Farm Animals	0	0	0	0	0
3. Other Animals					
Mink	0	33	108	50	191

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesteic, 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	L OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
			11/28/00

APHIS FORM (AUG 91

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

2000 ANNUAL REPORT OF RESEARCH FACILITY

Schering-Plough Animal Health Corp.
21401 West Center Road
Elkhorn, Nebraska 68022

Registration No. 47-R-0010

Column E Entries

I. Dogs:

A total of 52 dogs are listed in Column E. Eleven (11) dogs were part of a bacterial vaccine challenge development model study conducted according to European Union Council Directive for product registration 92/18/EEC, Part 7, C (1), C (2) and C (3). Pain and distress-relieving drugs were not utilized in these tests because they would mask the effects of the virulent challenge.

Fourteen (14) dogs were used in a viral vaccine dose titration study. The study was conducted in accordance with APHIS/VS General Licensing Considerations #800.200 (12 May 1995), APHIS/VS Memorandum 800.70 (29 May 1998), European Union Monograph 1998:0451; Directive 92/18/EEC, Title II, Parts 8 & 9; and Guidelines.

Twenty-seven (27) dogs were used in a viral vaccine immunogenicity study. The study was conducted in accordance with APHIS/VS General Licensing Considerations #800.200 (12 May 1995), APHIS/VS Memorandum 800.70 (29 May 1998), European Union Monograph 1998:0451; Directive 92/18/EEC, Title II, Parts 8 & 9; and Guidelines.

II. Cats:

The twelve cats listed in Column E were used in a dose titration study for a viral vaccine. The study was conducted in accordance with APHIS/VS General Licensing Considerations #800.200 (12 May 1995), APHIS/VS Memorandum 800.70 (29 May 1998), European Union Monograph 1998:0451; Directive 92/18/EEC, Title II, Parts 8 & 9; and Guidelines.

Schering-Plough Animal Health Corp.
21401 West Center Road
Elkhorn, Nebraska 68022

III. Guinea Pigs:

A total of 128 guinea pigs are listed in Column E. The guinea pigs were used in eleven bacterial vaccine potency tests according to APHIS, 9CFR sections 113.106 or 113.107. While all the vaccinated animals were protected from death, the nature of the challenge material induced swelling and pain at the injection sites for the duration of the three-day study.

III. Hamsters:

A total of 1205 hamsters are listed in Column E. A total of 514 hamsters were used as unvaccinated controls or in the LD_{50} determination segments of potency tests for bacterin production. A total of 691 hamsters were used for *in vivo* challenge passage tests for bacterin production. Both tests were conducted according to USDA-mandated methods specified in APHIS, 9CFR sections 113.102 and 113.103 and Supplemental Assay Methods 609 and 610. These tests require illness or death as the end point. Pain and distress-relieving drugs were not utilized in these tests because they would mask the effects of the virulent challenge. In the potency test, all survivors are humanely euthanatized at the end of the 14-day observation period. In the challenge passage test, hamsters designated as liver donors and other surviving hamsters are humanely euthanatized as soon as possible.

2000 ANNUAL REPORT OF RESEARCH FACILITY

Schering-Plough Animal Health Corp.
21401 West Center Road
Elkhorn, Nebraska 68022

IV. Mink:

A total of 50 mink are listed in Column E. A total of 45 mink were used as unvaccinated controls or died despite pre-challenge vaccination as part of bacterin-toxoid and virus Potency tests conducted according to USDA mandated methods specified in APHIS, 9CFR sections 113.110 and 113.204. Pain and distress-relieving drugs were not utilized in these tests because they would mask the effects of the virulent challenge. Surviving mink were humanely euthanatized as soon as possible at the completion of a study.

Three mink were used as unvaccinated controls as part of a bacterin serial release test for a conditionally licensed bacterin-toxoid for cattle. The mink potency test was conducted according to APHIS, 9CFR sections 113.110 (c).

2000 ANNUAL REPORT OF RESEARCH FACILITY

Schering-Plough Animal Health Corp.
21401 West Center Road
Elkhorn, Nebraska 68022

SUMMARY OF EXCEPTIONS TO THE REGULATIONS AND STANDARDS – WITH EXPLANATIONS

1. In two challenge model studies involving zoonotic infectious bacterial diseases in a total of 27 dogs, the principal investigator requested changes in sanitizing and exercise requirements to reduce cross-contamination among treatment groups and for biosafety concerns. These changes were approved by the IACUC.

2. In one viral vaccine dose titration study and one viral vaccine duration of immunity study involving a total of 53 dogs, the principal investigator requested changes in sanitizing and exercise requirements due biosafety concerns about the zoonotic virus. These changes were approved by the IACUC.

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-00A-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

47-R-0026

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

BIOCOR ANIMAL HEALTH INC
2720 N 84TH ST
FOUNDERS HALL
OMAHA, NE 68134

NOV 30 2000

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)*

Building C, 2724 N. 84th Street See Attached	27484 King Avenue
Omaha, NE 68134	Rusmore, MN 56187

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	4	55			55
5. Cats		33			33
6. Guinea Pigs	4	222			222
7. Hamsters	30	2620		4375	6995
8. Rabbits			464		464
9. Non-human Primates					
10. Sheep	27	55			55
11. Pigs		6			6
12. Other Farm Animals					
Cattle		116			116
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.

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
		11-29-00

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

Attachment to form 7023

Testing is performed in hamsters in accordance with 9 CFR 113.101, 113.102, 113.103 and 113.104 to release USDA licensed product containing leptospira organisms. The hamsters listed in column E were either used for passage of the challenge cultures or as negative control animals which were challenged with viable organisms. 9 CFR regulations do not allow the administration of any treatment concurrent with testing.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 47-R-0026 CUSTOMER NO. 1809

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

BIOCOR ANIMAL HEALTH, INC.
2720 N 84TH ST
OMAHA, NE 68134

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)*

BIOCOR ANIMAL HEALTH, INC
OMAHA, NE 68134

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary. See 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		60			60
5. Cats		11			11
6. Guinea Pigs			656		656
7. Hamsters	44	5809		3696	9505
8. Rabbits		248			248
9. Non-Human Primates					
10. Sheep	41	120			120
11. Pigs					
12. Other Farm Animals					
Cattle	12	105			105
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/02/2004

1. Registration Number: 47-R-0026 / 1809

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

Hamsters (3696)

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

Leptospira potency testing (9 CFR 113.101, 102, 103 and 104).

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)

The tests are required by regulation as a proof of Leptospiral vaccine potency to be conducted on each serial of vaccine produced. Death of hamsters in this test has been used for many years to indicate lack of protection from leptospirosis. Because the vaccine is given at fractional dose, the test amounts to a protective endpoint determination for the vaccine being tested. Leptospirosis in hamsters almost always results in acute onset and rapid death. The rapid progression of the disease in the hamster gives little opportunity for intervention. Furthermore, pathology would likely be impacted by the use of anti-inflammatories. For this reason, neither Biocor Animal Health nor USDA/CVB-L uses any substance to reduce pain or distress. The impact on length of disease, duration and severity, which might occur with use of pain medications, is not known. Use of any drugs, therefore, would invalidate the scientific value of the protection endpoint determined by the test. Lack of confidence in the endpoint would render the test itself useless for judging vaccine potency. USDA/APHIS/CVB is engaged in developing in vitro potency test alternatives for products that require this test. Until such time as a validated USDA/APHIS/CVB-approved alternative is available, this standard test is obligatory. No alternatives exist at this time, and no CVB approved means of relieving pain and distress for this use of hamster are yet available.

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: APHIS, 9 CFR 113.101, 102, 103 and 104. CFR:

Approval Status:
Approved/Disapproved By:
Date:

Disapproved Reason:

17-Dec-03

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **REGISTRATION NO.** 48-R-0004 **CUSTOMER NO.** 1400

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*

BAYER CORP. AGRIC. DIVISION, TOXICOLOGY
BAYER RESEARCH PARK
17745 S METCALF AVE
STILWELL, KS 66085
(913) 433-5221

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.) 17745 S. Metcalf, Stilwell, KS 66085

FACILITY LOCATIONS*(sites)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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		464		12	476
5. Cats		149		22	171
6. Guinea Pigs		64		0	64
7. Hamsters		0			0
8. Rabbits		0			0
9. Non-Human Primates		0			0
10. Sheep		0			0
11. Pigs		0			0
12. Other Farm Animals		0			0
13. Other Animals		0			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, 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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		12-15-03

APHIS FORM 7023 (AUG 91)

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

PART 1 - HEADQUARTERS

DEC 16 2003

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	48-R-0004
Customer Number:	1400
Facility:	BAYER CORP. AGRIC. DIVISION, TOXICOLOGY BAYER RESEARCH PARK 17745 S METCALF AVE STILWELL, KS 66085 (913) 433-5221

SITE 1
17745 S. METCALF
STILWELL, KS 66085

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 48-R-0004

2. Number 24 (22 which experienced unalleviated pain or distress) of animals used in study.

3. Species (common name) Feline of animals used in study.

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

   Two groups of 12 kittens each received an oral dose of a dermal product with an IACUC approved procedure. Clinical signs were limited to salivation (5 of 24) and vomiting (17 of 24). Animals were under observations recorded at 1, 2, 4 and 6 hours on the day of dosing.

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)

   The distress was limited to the salivation of 5 cats and vomiting in 17 along with gastric upset for two hours in 4 cats of 17, which resolved on its own. The purpose of this study was to define and characterize the toxicological properties of an experimental drug (test article). Alleviation of pain or distress could mask the effects of the test article, invalidating the test. Professional veterinary care is available 24 hours a day if there is an extreme adverse reaction or health conditions that would result in obvious pain to the animal, or reactions of a life-threatening nature.

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):

   Target Animal Safety Guidelines for New Animal Drugs, Office for New Animal Drug Evaluation ENTER FOR Veterinary Medicine, Food and Drug Administration, #56, July 10, 2001.

   Agency _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 48-R-0004

2. Number 32 {3 which experienced unalleviated pain or distress} of animals used in study.

3. Species (common name) Canine of animals used in study.

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

   The dogs were being fed a test compound which was mixed with their food to evaluate the toxicity of the compound in dogs over a 90 day period. The compound caused the formation of calculi in the urinary tract (i.e., the kidneys, bladder, ureter, and urethra) of the males. In the three dogs, the calculi caused pain/distress as demonstrated by: 1) a marked reduction in food consumption for one dog for approximately 10 days, with normal behavior and no signs of distress, until day eleven when the dog became lethargic. 2) The other two dogs were found one morning to be extremely lethargic and in apparent distress. Prior to this the two dogs had normal behavior and showed no signs of distress.

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)

   The pain/distress of the dogs was based on their behavior. As soon as the dogs became lethargic, indicating pain, the dogs were euthanized by injection.

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 EPA CFR OPPTS 870.3150

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 48-R-0004

2. Number 16 {1 which experienced unalleviated pain or distress} of animals used in study.

3. Species (common name) Canine of animals used in study.

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

   Animals were orally gavaged with a pharmaceutical compound to evaluate the toxicity of the compound over two weeks. Administration of the test article may have caused excessive vomiting.

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)

   The animal died within 30 minutes of experiencing respiratory distress. There was no time for intervention that could have prevented the death of the dog. Moreover, the purpose of this study was to define and characterize the toxicological properties of an experimental drug (test article). Alleviation of pain or distress could mask the effects of the test article, invalidating the test.

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):

   Prior to the approval of a new drug, the sponsor must show that the drug is safe for use as recomended in the proposed labeling [21 CFR 514.1(b)(8) and section 512 (d) of the Federal Food, Drug and COSMETIC Act].

   Agency _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 48-R-0004

2. Number 40 {2 which experienced unalleviated pain or distress} of animals used in study.

3. Species (common name) Canine of animals used in study.

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

   Animals were being orally gavaged with a pharmaceutical compound to evaluate the toxicity of the compound over a 90-day period. Two animals experienced bloody, loose stools. It was unclear whether administration of the test article or something else caused this condition.

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)

   It is important in studies of this type to determine what the maximum tolerated dose is. Pain & Distress (diarrhea) resolved within 24 hours. The purpose of this study was to define and characterize the toxicological properties of an experimental drug (test article). Alleviation of pain or distress could mask the effects of the test article, invalidating the test. Professional veterinary care is available 24 hours a day if there is an extreme adverse reaction or health conditions that would result in obvious pain to the animal, or reactions of a life-threatening nature.

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):

   Prior to the approval of a new drug, the sponsor must show that the drug is safe for use as recomended in the proposed labeling [21 CFR 514.1(b)(8) and section 512 (d) of the Federal Food, Drug and COSMETIC Act].

   Agency _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 48-R-0004

2. Number 32 {3 which experienced unalleviated pain or distress} of animals used in study.

3. Species (common name) Canine of animals used in study.

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

   Animals were orally gavaged with a pharmaceutical compound to evaluate the toxicity of the compound over 28-days. Administration of the vehicle control or test article induced excessive vomiting.

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)

   All animals died within 30 minutes of experiencing respiratory distress. There was no time for any intervention that would have prevented death. Moreover, the purpose of this study was to define and characterize the toxicological properties of an experimental drug (test article). Alleviation of pain or distress could mask the effects of the test article, invalidating the test. Professional veterinary care is available 24 hours a day if there is an extreme adverse reaction or health conditions that would result in obvious pain to the animal, or reactions of a life-threatening nature.

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):

   Prior to the approval of a new drug, the sponsor must show that the drug is safe for use as recomended in the proposed labeling [21 CFR 514.1(b)(8) and section 512 (d) of the Federal Food, Drug and COSMETIC Act].

   Agency _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 48-R-0004

2. Number 20 {3 which experienced unalleviated pain or distress} of animals used in study.

3. Species (common name) Canine of animals used in study.

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

   Animals were orally gavaged with a pharmaceutical compound to evaluate the toxicity of the compound over a 7-day period. Two high dose females had diarrhea, were anorexic & lethargic for 48 hours. One mid dose female had similar signs for 24 hours.

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)

   All animals experiencing pain & distress were in the mid or high dose groups. It is important in studies of this type to determine what the maximum tolerated dose is. Pain & Distress (diarrhea) resolved within 24 hours. The purpose of this study was to define and characterize the toxicological properties of an experimental drug (test article). Alleviation of pain or distress could mask the effects of the test article, invalidating the test. Professional veterinary care is available 24 hours a day if there is an extreme adverse reaction or health conditions that would result in obvious pain to the animal, or reactions of a life-threatening nature.

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):

   Prior to the approval of a new drug, the sponsor must show that the drug is safe for use as recomended in the proposed labeling [21 CFR 514.1(b)(8) and section 512 (d) of the Federal Food, Drug and COSMETIC Act].

   Agency _____ CFR _____

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 48-R-0107 CUSTOMER NO. 14439

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA. Include Zip Code)*

BIOMUNE CO.
8906 ROSEHILL RD
LENEXA, KS 66215
(913) 894-0230

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	3	0	0	3
7. Hamsters					
8. Rabbits	0	253	0	0	253
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNE
		Oct. 17, 03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTEI

OCT 21 2003

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	48-R-0107
Customer Number:	14439
Facility:	BIOMUNE CO. 8906 ROSEHILL RD LENEXA, KS 66215 (913) 894-0230

8906 ROSEHILL RD
LENEXA, KS 66215

OCT 21 2003

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 2150

...verse side for additional information

Interagency Report Control No. 0186-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 50-R-001 SOR0001

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

NOV 15 1999

41

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Haskell Laboratory
E. I. du Pont de Nemours and Company
P.O. Box 50, Elkton Road
Newark, DE 19714-0050

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)*

Haskell Laboratory Building 1

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	756	0	69*	825
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0
* please see attachment for explanation					

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
		11/4/99

APHIS FORM 7023
(AUG 91)

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

PART 1 - HEADQUARTERS

50R0001

Newark, DE 19714-0050

DuPont Haskell Laboratory

NOV 15 1999

November 4, 1999

Elizabeth Goldentyer, DVM
USDA, APHIS, REAC
Eastern Regional Office
920 Main Campus Drive
Suite 200, Unit 304O
Raleigh, NC 27606

Dear Dr. Goldentyer:

To address the issue of the category E animals in our annual report, I am providing a list of eight types of skin irritation studies and four types of eye irritation studies which were conducted at the Laboratory. All study protocols and SOP's were reviewed by the Laboratory's Institutional Animal Care and Use Committee (IACUC).

Skin Irritation Studies

1. Skin Corrosion Test – A skin corrosion study is conducted to determine an International Maritime Dangerous Code (IMDC) packaging class for chemicals.

2. Skin Irritation Study in Rabbits – The purpose of this study is to supply safety assessment information and to enable companies to file for pre-manufacturing notifications (PMNs).

3. Skin Irritation Study Under Potential Use Conditions – The purpose of this study is to supply safety assessment information and to enable companies to file for pre-manufacturing notifications (PMNs).

4. Skin Irritation Screen – The purpose of this study is to supply safety assessment information for Discovery compounds.

5. Acute Dermal Irritation/Corrosion Study – This study is conducted for the registration of agricultural products with the Organization for Economic Cooperation and Development (OECD) and European Economic Community (EEC). The Acute Dermal Irritation/Corrosion Test is also conducted to aid in determining a Workplace Hazardous Material Identification System (WHMIS) rating for Canada and a Hazardous Material Identification System (HMIS) rating for the United States.

6. Skin Toxicity Screen – This study is designed to determine the toxicity by dermal absorption of substances of similar chemical structure to substances previously shown to be toxic by the dermal route. This study is conducted for Discovery compounds.

7. Skin Absorption Approximate Lethal Dose Study – This study is performed for safety assessment and to determine a packaging class for the transportation of chemicals.

8. Acute Dermal Toxicity Study – This study is conducted for the registration of agricultural products with EPA FIFRA.

Eye Irritation Studies

1. Eye Irritation Study – The purpose of this study is to supply safety assessment information and to enable companies to file for pre-manufacturing notifications (PMNs).

2. Primary Eye Irritation Study – This study is conducted for the registration of agricultural products with EPA FIFRA.

3. Acute Eye Irritation/Corrosion Study – This study is conducted for the registration of agricultural products with the Organization for Economic Cooperation and Development (OECD) and European Economic Community (EEC).

4. Eye Irritation Screen – The purpose of this study is to supply safety assessment information for Discovery compounds.

The IACUC approved the conduct of these studies without the use of anesthetics, analgesics or tranquilizing drugs because the use of such drugs could adversely influence the experimental compound's effect of the animal or alter the animal's reaction to the experimental compound, resulting in invalid interpretation of the clinical signs by the scientists. There is very little information in the scientific literature that directly addresses this issue. Two recent articles[1,2] have indicated that there are no specific topical ocular anesthetics that should be used in ocular irritancy testing. Ocular topical anesthetics may delay corneal healing, decrease lacrimation and increase the permeability of corneal epithelium. These documented adverse effects suggest that the use of these drugs in ocular irritancy tests may confound results. In addition, the disruption of natural ocular protective barriers might increase the toxicity of the test substances.

The use of systemic analgesics has also been considered. The dearth of information in the scientific literature addressing potential effects of experimental compound permeability, and describing the physiologic, psychologic, and pharmacologic effects of these analgesics on the rabbit, makes their use inappropriate in our routine testing programs.

50R0001

DuPont actively supports research programs to develop scientifically acceptable refinements and alternative to animal testing. At present, there are no validated alternatives that would completely replace animal tests which are required by national and international laws and regulations.

Sincerely,

NOV 15 1999

References

Durham, Robert A., *et al.* "Topical Ocular Anesthetics in Ocular Irritancy Testing: A Review," *Laboratory Animal Science*, Volume 42, No. 6, December 1992, pp. 535-541.

Seabaugh, V.M., *et al.* "Use of Ophthalmic topical Anesthetics," *Fd Chem. Toxic.*, Volume 31, No. 2, 1993, pp. 95-98.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 57-R-0005 **CUSTOMER NO.** 900

FORM APPROVED
OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF GEORGIA
VP FOR RSCH, BOYD GRAD RSCH CTR RM 612
ATHENS, GA 30602

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
cows		74	17		91
goats		29	39		68
9-banded armadillo		2			2
house mouse		74			74
short tail shrew		7			7
cotton rat		351			351
white footed mouse		24			24
deer		31			31

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/22/2004

APHIS FORM 7023A (AUG 91) **(Replaces VS FORM 18-23 (Oct 88), which is obsolete**

PART 1 - HEADQUARTERS

APHIS Form 7023 Additional Reported Sites

The following additional sites have been reported by the facility. The reported sites have not been verified by APHIS and have been provided by the facility solely for completeness of the APHIS Form 7023 Annual Reporting submission.

Registration Number: 57-R-0005
Customer Number: 900
Facility: UNIVERSITY OF GEORGIA
VP FOR RSCH, BOYD GRAD RSCH CTR RM 612
ATHENS, GA 30602

College of Pharmacy, Main Campus
University of Georgia
Athens, GA 30602
Life Sciences Building, Franklin College of Arts and Sciences, Main Campus
University of Georgia
Athens, GA 30602
College of Veterinary Medicine, Main Campus
College of Veterinary Medicine, Riverbend and Oconee County Farms
University of Georgia
Athens, GA 30602
Savannah River Ecology Laboratories
Aiken, South Carolina

1785
The University of Georgia

Office of the Vice President for Research
Animal Care and Use Program

Phone: (706) 542-5933

Fax: (706) 542-5638

IACUC-Approved Exceptions to the Regulations
57-R-005

At the September 16, 2004 IACUC meeting, an exception to the regulations was reviewed and approved. Dr. Scott A. Brown submitted the exception as a modification of a previously approved protocol, [redacted] Dr. Brown requested an exception to cage sanitation practices in his research using cats. The cats have implanted telemetry devices and their home cages have receivers and associated wiring for the telemetry devices fixed to them. It is very difficult to remove and then reinstall these fixed elements for mechanized sanitation of the cages. It was proposed that the floor panels, litter boxes, hammocks, and divider panels, all surfaces that the cats have substantial contact with, be sanitized on the usual schedule of every two weeks. Only the stainless steel frame with attached woven wire panels would not be sanitized on this schedule and would be washed at the conclusion of the study, a period of 96 days total.

608 Boyd Graduate Studies Research Center
Athens, Georgia 30602-7411

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 2150

#34

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 50-R-0010

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

DuPont Pharmaceuticals Research Labs
P.O. Box 80400, E400/2710
Wilmington, DE 19880
(302) 695-1190

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.) 10/1/00 - 9/30/01

FACILITY LOCATIONS *(Sites)*

Experimental Station - Bldg. 400, Wilmington, DE

Stine-Haskell Laboratories - Bldg. S320, Newark, DE

11-23-2001 RCVD

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	99	545	944	16	1505
5. Cats	0	0	0	0	0
6. Guinea Pigs	8	1	54	0	55
7. Hamsters	0	124	1061	0	1185
8. Rabbits	88	31	1366	0	1397
9. Non-human Primates	0	31	0	0	31
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		Nov 14, 2001

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

ADDENDUM TO ANNUAL REPORT OF DUPONT PHARMACEUTICALS COMPANY
RESEARCH FACILITY (50-R-0010) FOR PERIOD ENDING 9/30/01

Explanation of Category E Animals

Safety Assessment:

All dogs reported were used in IACUC approved safety assessment studies to determine potential toxicity and toxicokinetic effects of novel compounds to be used for human treatment. There were five studies that resulted in 10 animals showing various clinical signs that resulted in a category E classification.

In one study 1 dog was administered a novel compound (high-dose range) orally. On day 20 of a 35 day study, the dog was inappetent, had a hunched posture, decreased skin turgor and pale mucous membrane color. It was provided supportive veterinary care in the form of oral and subcutaneous fluid administration and dietary supplementation. Its condition improved and it remained on study.

Another study involved four dogs that were orally dosed twice daily (one mid-dose range and three high-dose range). On day 4 of dosing in a 6 month study, one dog (mid-dose) exhibited convulsions approximately one hour post dosing. The animal recovered within five minutes and was alert and responsive. It fully recovered without any additional episodes and continued on study. On day 9 of the same study, three dogs exhibited tonic-clonic clusters of convulsions approximately 1.5 hours after the second daily dose, and this continued at least 3-4 hours post dosing. The convulsions became less severe during this observation period. They also exhibited emesis, hypersalivation, and tremors/muscle fasciculations at rest. These three dogs were euthanatized the morning of day 10 for humane reasons.

On day 7 of a two week study, 2 dogs that were orally dosed once daily (high dose range) exhibited emesis after dosing. Since dose day 1, they had also exhibited mild ataxia, forelimb and hindlimb propriceptive deficits, and tremors from which they usually recovered within a few hours post dosing. However, by day 7 the signs were longer in duration, and they each had lost about 10-15% body weight. They were inappetent, dehydrated, and had diarrhea. One dog also exhibited dyspnea, and it was euthananized immediately. The second dog (less severely affected) was euthanatized on day 10 when its condition didn't improve.

Another project involving a sheep red blood cell (SRBC) immunization protocol resulted in 3 dogs exhibiting an anaphylactic response. On day 10 of a 45 day study, two dogs exhibited emesis, had pale mucous membranes with a delayed capillary refill time, and were prostrate within minutes of being dosed intravenously with SRBC. Both dogs fully recovered within 45 minutes of the acute reaction, and remained on study without any further problems. One other dog was used in a 28 day study using a similar protocol. It became prostrate, hypothermic and dyspneic on day 12 immediately after intravenous dosing, and died acutely.

In all cases, the use of anesthetics, analgesics or tranquilizers was precluded due to the possibility of interaction with the test compound, thus invalidating the studies. The amount of pain and distress, if any, could not be determined.

All safety assessment studies were conducted to fulfill approval of drug entities for use in humans required by the Food and Drug Administration, Department of Health and Human Services, Federal Register, Title 2, CFR Part 58,Volume 60, No.40, pp. 11264-11268; March 1, 1995.

Drug Metabolism / Pharmacokinetics:

In one study, two dogs used in an IACUC approved pharmacokinetic study to determine the metabolic properties of a novel compound were administered (oral) a single high-dose concentration. Within 15 minutes of dosing, the animals exhibited emesis. Approximately 20 minutes post dosing, one dog exhibited tonic-clonic seizures that culminated into status epilecticus. The dog was euthanatized within

40 minutes of dosing. The second dog became ataxic and started exhibiting "tics" at 40 minutes post dosing. It was immediately euthanatized.

In both cases, the use of anesthetics, analgesics or tranquilizers was precluded due to the possibility of interaction with the test compound, thus invalidating the studies. The amount and degree of pain and distress, if any, could not be determined.

All Drug Metabolism/ Pharmacokinetic studies were conducted to fulfill approval of drug entities for use in humans required by the Food and Drug Administration, Department of Health and Human Services, Title 21, CFR 312.

Experimental Station

A total of four dogs used in IACUC approved discovery studies were classified as Cateogry E based on clinical presentations while being used for various projects. On two separate occasions involving a preclinical pharmacology study, a dog experienced acute adverse reactions after dosing. One dog died within minutes of being administered a test compound by oral gavage. During another study, a dog collapsed within a few minutes after being administered a test compound by oral gavage. It was prostrate, non-responsive to stimuli, exhibited shallow respiration, dilated pupils, and had a weak pulse. It was intubated and administered oxygen; however, within minutes of initiating resuscitation, the dog died. In each case there was evidence of compound aspiration.

One dog in a preclinical pharmacodynamics study with an antithrombotic agent experienced emesis at one hour post oral dosing. Emesis continued intermittently and became red tinged. Five hours post-dosing, the dog appeared normal, but did not eat. The following day, it was quiet, inappetent, and had emesis and feces that were red tinged. Examination by a veterinarian determined that the use of analgesics, anesthetics, or tranquilizers was contraindicated. With little clinical improvement 48 hours after the initial signs, the dog was euthanatized.

One dog used in a project involving a sheep red blood cell (SRBC) immunization protocol exhibited an acute anaphylactic response. It exhibited several bouts of emesis within five minutes of dosing and continued several times during a 20 minute period. The dog fully recovered within 45 minutes of the acute reaction, and remained on study without any further problems.

In each case, the amount of pain and/or distress could not be determined. The use of anesthetics, analgesics or tranquilizers was precluded due to the possibility of interaction with the test compound, thus invalidating the studies.

Addendum II Summary of IACUC Approved Exceptions to USDA Regulations

Stine Haskell Research Center (Drug Metabolism/Pharmacokinetics):

Dogs used in IACUC approved pharmacokinetic studies were administered radiolabelled (^{14}C or ^{3}H) test compounds to determine routes of excretion. Seven (7) dogs were exempt from exercise until the level of radioactivity in urine and feces reached acceptable background readings, in order to allow accurate recordings of compound disposition and not to contaminate the environment. The length of time animals were exempt from exercise ranged from 24 hours to 14 days. Two of the seven dogs were used twice on studies which required exemption of up to 3 days.

Experimental Station

A group of five squirrel monkeys were singly housed for nine months during the reporting year in order that feed intake could be measured for individual animals. Environmental enrichment and varied food items were provided. The animals were housed in caging that provided 43% more space than required. Visual, olfactory and auditory contact with conspecifics was not interrupted.

The cage changing interval was extended one or a maximum of two days for hamsters involved in a feeding study in order to avoid having cage changing occur just prior to a critical part of the study such as obtaining blood for clinical chemistry values where the disturbance of cage changing could have an adverse effect on the parameter(s) being studied.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 57-R-0012 **CUSTOMER NO.** 907

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

GEORGIA STATE UNIVERSITY
33 GILMER ST UNIT 3
ATLANTA, GA 30303

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)*

ANIMAL CARE & LANGUAGE RESEARCH CENTER
ATLANTA, GA 30303

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	665	1396	3097		4493
8. Rabbits		7	145		152
9. Non-Human Primates		18			18
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Grass rat		31	227		258
Ferrets	6	3	65		68
Octodon Degus		2	3		5

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/28/2004

APHIS FORM 7023 **(AUG 91)** **(Replaces VS FORM 18-23 (Oct 88), which is obsolete**

PART 1 - HEADQUARTERS

EXCEPTIONS TO USDA REGULATIONS

3.28(b)(3)(i)
"The interior height of any primary enclosure used to confine hamsters shall be at least 6 inches."

We sometimes house dwarf hamsters in 5 inch cages because it is documented that 6 inch cages are detrimental to their growth [Gilman WC, et al. "Effect of the New USDA Cage Height Standard on Body Weights of Weanling and Djungarian Dwarf Hamsters (*Phodopus sungous*). Contemporary Topics in Lab An Sci, 32(1):17-19, 1993.]

Number of animals effected: 2153 dwarf hamsters (note: 484 were never in research)

3.28(b)(3)(ii)
"A nursing female hamster, together with her litter, shall be housed in a primary enclosure which contains no other hamsters..."

All of our breeding female dwarf hamsters with litters are housed with the adult male sire because our experience is that, unlike common golden hamsters, the Siberian dwarf hamster male is not injured by the female and he participates in the rearing of the young such that pup survival is higher when the sire is present.

Number of animals effected: 131 breeding pairs (131 males and 131 females)

3.31(a)(1)

"[Hamster] enclosures shall be sanitized at least once every 2 weeks ..."

We sometimes do not change hamster cages for up to a maximum 4 weeks due to the experimental needs of IACUC-approved research involving territorial aggression and circadian rhythms.

Number of animals effected: 1,347 hamsters

Policy #12
"When a database search is the primary means of meeting [the requirements to search for alternatives], the narrative must, at a minimum, include ... the period covered by the search."

If an entire database is searched, it may not be possible to determine the period covered by the search. For example, The National Library of Medicine's "PubMed" database goes back to 1996 for some major journals, but coverage of other journals begins in various different years (not necessarily starting with the earliest year that the journal was published). Therefore, instead of reporting the period covered by the search, we require a statement that the entire database was searched without limitations on a particular date.

***Guide*, p. 18**

"Zoonosis surveillance should be a part of an occupational health program."

Because rabbits and some rodents are purchased from vendors who guarantee them free from known zoonotic agents, zoonosis surveillance is not done routinely. The wild derived rodent colonies ay GSU have repeatedly tested negative for zoonotic agents. Ferrets are vaccinated against rabies by the vendor. Ferrets born in house are not vaccinated for rabies due to exclusion of potential transmitters of this disease from the facilities.

***Guide*, p. 40**

"watering devices, such as drinking tubes ... should be checked daily to ensure their proper maintenance, cleanliness, and operation."

Even if we had the personnel to shake very water bottle every day of the year, this would probably not be good use of their time. Instead, our SOP for daily room checks includes the following statement:

> Visually check the health and condition of each animal.
> Compare the water level in the bottles and elimination
> and consumption in each cage relative to the others.
> If any animal appears to be eating, drinking, or eliminating
> less than the others, check the function of the water bottle.

***Guide*, p. 75**

"Temperature is best regulated by having thermostatic control for each room. Use of zonal control for multiple rooms can result in temperature variations between the 'master-control' animal room and the other rooms in the zone, because of differences in animal densities within the rooms and heat gain or loss in ventilation ducts and other surfaces within the zone."

The Kell second floor facility has zonal temperature controls, but the 'master-controls' are in the outdoors (where animals are not housed), so that the number of animals in the 'master-control room' doesn't effect the other rooms. Since the facility was opened, temperatures have been controlled within the required 5% fluctuation.

Reviewed and approved by the GSU Institutional Animal Care and use Committee (IACUC) on 03/26/04.

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 21

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 57-R-0117
CUSTOMER NUMBER: 1709

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1130 Crosstown Court
Peachtree City, GA 30269

NOV 2 6 2004

Telephone: (770) -486-0077

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs (porcine)			3		3
12. Other Farm Animals			0		0
13. Other Animals			0		0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-24-

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 21

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 57-R-0117
CUSTOMER NUMBER: 1709

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1130 Crosstown Court
Peachtree City, GA 30269

NOV 2 6 2004

Telephone: (770) -486-0077

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs (porcine)			3		3
12. Other Farm Animals			0		0
13. Other Animals			0		0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-24-

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

Institutional Animal Care and Use Committee

Protocol for Animal Usage

IACUC number: 2004-01 *Date laboratory is requested: August 7, 2004*

1. **Animal Species requested:** Pigs (porcine)

2. **Number of Animals requested:** Three (3)

3. **Give rational for involving animal and the appropriateness of the species and numbers of animals used:**

   There is no exact substitute for animals during the surgical procedure. Tissue handling, texture and blood supply make it most suited for mimicking human tissue. Pigs have urogenital and digestive tract that is similar to humans with some exceptions. Dogs might provide better anatomical models, however,. There is not enough improvements to warrant their use. Pigs are often used as models for human surgical procedures and are sufficient for that purpose. It is necessary to utilize new technique and instrumentation in animal models occasionally to reduce errors during surgery involving humans where unfamiliar instrumentation might result in adverse outcome.

   Three animals are being used for a total of 12 gynecologic surgeons and residents. Therefore, 4 surgeons will be utilizing each animal. This is a high ratio of surgeons to animal but will still allow each surgeon top complete the protocol.

4. **Provide a description of the proposed use of the animals.**

   The animals will have Endoscopic trocars placed in the abdomen. Insufflation of the abdominal with 12-15 mmHG carbon dioxide will facilitate viewing of the abdominal contents utilizing rigid endoscopy. The stapling instruments will be used in the abdomen. Several techniques will be demonstrated and performed. The procedures will be taught and facilitated by surgeons with known expertise in their field. Additional assistance will be provided by Eticon Endosurgical surgical representative who have had explicit training in the use of the products in question. A novel device, called the LaprAssist® may be used to allow the surgeon's hand to be inserted into the abdomen. Either on both kidneys may be removed using minimally invasive surgery. Other abdominal procedures may be performed with minimally invasive surgery also, including cholecystectomy, urinary cystectomy, colectomy or other appropriate procedures that may

demonstrate the indications and limitations of this device. Some surgeons may be trained, depending on their expertise, performing minimally invasive surgery. The patients abdomen may be opened to perform open surgical techniques also. A Harmonic Scalpel™ will be used to coagulate and transected to aid in surgeon understanding of the limits of this modality. Likewise, tissues will be divided using the modality to enhance surgeon's understanding of its use.

5. **Describe procedures designed to assure that discomfort and pain to the animals will be limited to that which is unavoidable for the conduct of the scientifically valuable research, including provision for the use of analgesic, anesthetic and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to the animal.**

   The animals will arrive at the facility by truck or trailer approximately an hour prior to anesthesia. They will remain in the transport device until they can be injected with an anesthetic agent. The anesthetic agent will cause unconsciousness. At that time, they will be transported into the facility and intubated to provide inhaled anesthetic gases (Isoflurane and Oxygen). They will be maintained at a surgical place of anesthesia throughout the procedures. Assisted ventilation will be provided manually or with a mechanical ventilator. Each animal will be monitored by a technician or veterinarian to assure the animal is maintained at a surgical plane of anesthesia Paralytic agents will not be used under any circumstances. A veterinarian will be supervising the procedure from beginning to end to assure compliance. Each animal will be euthanized at the termination of the surgical procedures and not be allowed to recover consciousness prior to euthanasia.

6. **Describe the euthanasia method used.**

   An intravenous injection of a concentrated barbiturate solution that is produced commercially for euthanasia will be used. Presently this solution brand name is Beuthnasia™.

   I approve this protocol

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 58-R-0041 **CUSTOMER NO.** 909

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

MOTE MARINE LABORATORY
1600 KEN THOMPSON PKWY.
SARASOTA, FL 34236

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)*

MOTE MARINE LABORATORY SARASOTA, FL 34236	
MOTE MARINE LABORATORY SARASOTA, FL 34236	

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					
Manatees		2			2
Dolphins and whales		15			15

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/11/2004

APHIS FORM 7023 **(AUG 91)** **(Replaces VS FORM 18-23 (Oct 88), which is obsolete**

PART 1 - HEADQUARTERS

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 21! NOV 30 2004 See attached form for additional information. Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 64-R-0004
CUSTOMER NUMBER: 832

FORM APPROVED
OMB NO. 0579-0036

University Of Alabama @ Birmingham
Vh B10
1530 3rd Ave South
Birmingham, AL 35294

Telephone: (205) -934-3553

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	3	0	34	0	34
5. Cats	0	0	0	0	0
6. Guinea Pigs	84	40	308	0	348
7. Hamsters	0	0	10	0	10
8. Rabbits	52	503	402	0	905
9. Non-human Primates	34	15	148	0	163
10. Sheep	0	0	10	0	10
11. Pigs	0	0	401	0	401
12. Other Farm Animals					
13. Other Animals Cotton rats	25	114	0	0	114
Tree Shrews	68	65	59	0	124
Lemmings	51	15	0	0	15
Ferrets	0	0	16	0	16

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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)

SIGN.	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/29/04

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

11/29/04

IACUC Approved Exceptions to USDA Regulations or Standards (2004)

1. **Controlled food or water intake (i.e., feeding less than once a day and/or watering less than twice a day for an hour each time).**

   Ten non-human primates were on studies using controlled water intake as behavioral reinforcement. During the period of controlled water intake the animals received ad-libitum water and/or juice during the experimental sessions as behavioral reinforcement for executing the required tasks. Additional water/juice or fruits were given if necessary. The maximum continuous period of controlled water intake was six days, with unlimited access to water for at least 24 hours between controlled periods. Animals were weighed regularly while on study with no ill effects observed.

2. **Maintaining animals at temperatures and/or humidities outside the ranges specified by the standards.**

   N/A

3. **Not cleaning and/or sanitizing at required frequencies.**

   N/A

4. **Not providing diurnal lighting as required.**

   Light cycles in lemming housing areas were designed to mimic natural environmental conditions. Animals received short periods of light or dark depending on the season being studied. The rooms were 8 hours light/16 hour dark, or 16 hours light/8 hours dark, or 22 hour light/2 hours dark.

5. **Not meeting space requirements (including innovative enclosures).**

   N/A

6. **Exceptions from the exercise plan for dogs or exceptions from the psychological well-being plan for primates.**

   Primates were pair housed unless research parameters, health status or behavior required individual housing. Individually housed animals received environmental enhancement through food treats, access to puzzles and/or toys, interaction with caretakers, and the ability to see other animals of their species.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 64-R-0004 CUSTOMER NO. 832

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

12-03-2001 RCVD

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF ALABAMA @ BIRMINGHAM
UAB STATION VH B10
BIRMINGHAM, AL 35294
(205) 934-3553

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	6	0	85	0	85
5. Cats	4	0	17	0	17
6. Guinea Pigs	75	158	391	0	549
7. Hamsters	0	0	0	0	0
8. Rabbits	44	456	580	0	1036
9. Non-Human Primates	42	54	118	0	172
10. Sheep	0	0	75	0	75
11. Pigs	9	0	280	0	280
12. Other Farm Animals					
13. Other Animals					
chipmunks	1	7	0	0	7
ferrets	0	0	23	0	23
ground squirrels	0	4	0	0	4

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/28/01

APHIS FORM 7023 (AUG 91) Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 64-R-0004 | CUSTOMER NO. 832 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF ALABAMA @ BIRMINGHAM
UAB STATION VH B10
BIRMINGHAM, AL 35294
(205) 934-3553

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Lemmings	80	50	134	0	184
Tree Shrews	56	3	42	0	45

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquillzing 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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/28/01

APHIS FORM 7023A) (AUG 91) (Replaces VS M 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

IACUC Approved Exceptions to USDA Regulations or Standards (2001)

1. **Controlled food or water intake. (i.e., feeding less than once a day and/or watering less than twice a day for an hour each time).**

   Fifteen (15) nonhuman primates were on studies using controlled water intake. Water was withheld overnight prior to testing. Animals received water and/or juice during testing and had free access to water for several hours following testing. Animals were weighed regularly while on study with no ill effects observed. The maximum continuous period of controlled water intake was 5 days. At least two days each week animals received unlimited access to water.

2. **Maintaining animals at temperature and/or humidity outside the ranges specified by the standards.**

   N/A

3. **Not cleaning and/or sanitizing at required frequencies.**

   N/A

4. **Not providing diurnal lighting as required.**

   Light cycles in Lemming housing areas are designed to mimic natural environmental conditions. Animals receive short periods of light or dark depending on the season being studied (6 hrs.light/18 hrs. dark or 22 hrs. light/2 hrs. dark).

5. **Not meeting space requirements (including innovative enclosures).**

   N/A

6. **Exceptions from the exercise plan for dogs or exceptions from the psychological well-being plan for primates.**

   In all cases the exceptions to 9CFR3.8 were due to a need to restrict the animal's activity post-operatively as recommended by the veterinarian. Exercise restriction lasted for periods of only 1-2 days.

   Primates were pair housed unless research parameters, health status or behavior required individual housing. Individually housed animals continued to receive environmental enhancement through food treats, access to puzzles and/or toys, interaction with caretakers, and the ability to see other animals of their species.

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 21!

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 65-R-0002
CUSTOMER NUMBER: 837

FORM APPROVED
OMB NO. 0579-0036

Mississippi State University
P.O. Box 6343
617 Allen Hall
Mississippi State, MS 39762

Telephone: (662) -325-3570

NOV 2 4 2004

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	159	90	0	249
5. Cats	0	38	7	0	45
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	12	0	0	12
8. Rabbits	0	0	82	0	82
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	3	21	0	24
11. Pigs	0	52	0	0	52
12. Other Farm Animals					
Cattle	0	5	41	0	46
13. Other Animals					
Horses	0	36	44	0	80
Black Bear	0	1	0	0	1
Wt. Tail Deer	0	44	0	0	44

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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)

SIGNATUR OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-19-04

APHIS FC (AU_ _ _ ,

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

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 65-R-0002

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Mississippi State University
P.O. Box 6343, 617 Allen Hall
Mississippi State, MS 39762

NOV 2 4 2004

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12. &/OR 13. Other *(List by species)*	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)
Cougar	0	1	0	0	1
Otter	0	1	0	0	1
Red Fox	0	1	0	0	1
Grey Fox	0	1	0	0	1
Bob Cat	0	14	0	0	14
Raccoon	0	1	0	0	1

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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 ONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-19-04

APHIS FORM 1023A
(AUG 91)

PART 1 - HEADQUARTERS

Mississippi State University
2003-2004 Annual Report
Animal Care and Use Sites

1. Wise Center
2. Harned Hall
3. Thompson Hall Annex (Spring only)
4. Blackjack Road Wildlife Unit
5. Farm Units (occasional biomedical use)
   a. Equine Unit and Pastures
   b. Physiology Unit
   c. Beef Unit and Pastures
   d. Dairy Unit and Pastures

EXEMPTION DETAILS

1. Up to 42 mature beagle dogs were used on projects studying the effects of antimicrobial compounds on periodontal disease progression. Those studies involved the maintenance of a dog colony in which dogs had various degrees of periodontal disease (no dogs were in pain or distress, however, during these studies). Various treatments were conducted on this animal model to effect a "cure," hoping that similar procedures could be used to treat periodontal disease in human beings.

   Beginning many years ago (around 1989), the investigator requested exemption from A.W.A.R. Section 3.11(6) for these reasons:

   Both animal and human research protocols involving gingivitis and periodontitis were studies of a microbial driven disease process. The studies of juvenile, middle aged, and geriatric patients (beagle dog colonies) were investigative studies of bacterial antigen, gingival attachment loss, increased soft tissue septic pocket depths, secondary bone loss, periodontal ligament necrosis, and tooth loss. In addition, secondary systemic effects were triggered by an oral microbial response.

   Applying sanitizing chemicals (or 180 degree Fahrenheit water) to runs coupled with the self-grooming nature of dogs (licking chemicals off feet, etc.) altered essential floor and/or oral microflora. Each of these runs was extremely clean and was scrubbed and rinsed daily using detergent and hot water. These cleaning methods were the same used on household eating utensils. In summary, sanitation methods must have been exempted from protocols or the models became invalid.

   The IACUC discussed in connection with every protocol involved alternative inoculation routes, use of hot (180 degree Fahrenheit) water only, increased health risks to dog, literature to support this premise, and other questions. Following considerable deliberations over several years, despite changing IACUC memberships, the committee accepted the investigator's premise and waived for this year of 2004 the A.W.A.R. sanitization requirement. These studies were, however, discontinued in September 2004.

2. On August 17, 2004, the IACUC approved an exemption to AW.A.R. Part 3, Section 3.6 primary enclosures (b) (3) cat litter. The exemption allow the removal of litter pans from individual cat cages in which the cats spend 4-5 hours only, in the morning while their large group pens are being cleaned. The 32 cats do not use their litter pans in these cages but do use litter pans in the group cages. If any cat is found urinating or defecating in its individual cage, however, a litter pan is place in that cage.

3. The small ruminant building at the College of Veterinary Medicine housed 4 vaccinated calves (3-4 months old) during this year. These SPF calves were infected experimentally with an intestinal nematode, and the feces collected to harvest ova over a 2-4 week period. The calves were then dewormed and sold. To ensure collection of viable ova, the IACUC granted an extension of the usual once every 2 week sanitization internal to as much as 4 weeks between sanitization of pens and pans. The pens (plastic pens) were cleaned daily. The calves were present from December 31, 2003 through March 8, 2004.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. **REGISTRATION NO.** 65-R-0002 **CUSTOMER NO.** 837

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*

MISSISSIPPI STATE UNIVERSITY
P.O. BOX 6343
617 ALLEN HALL
MISSISSIPPI STATE, MS 39762
(601) 325-3432

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	4	230	0	234
5. Cats	0	19	11	0	30
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	6	0	0	6
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	25	0	25
11. Pigs	0	47	18	0	65
12. Other Farm Animals					
Cattle	0	6	6	0	0
13. Other Animals					
wild mice	0	70	0	0	0
skunk ..	0	1	0	0	1
bear	0	1	0	0	1

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/10/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **REGISTRATION NO.** 65-R-0002 **CUSTOMER NO.** 837

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*

MISSISSIPPI STATE UNIVERSITY
P.O. BOX 6343
617 ALLEN HALL
MISSISSIPPI STATE, MS 39762
(601) 325-3432

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Goats	0	2	0	0	2
Mountain lion	0	1	0	0	1
Deer	0	64	0	0	64
Bobcats	0	17	0	0	17
Raccoon	0	1	0	0	1
Foxes	0	5	0	0	5

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/10/04

APHIS FORM 7023A (AUG 91)

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

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	65-R-0002
Customer Number:	837
Facility:	MISSISSIPPI STATE UNIVERSITY P.O. BOX 6343 617 ALLEN HALL MISSISSIPPI STATE, MS 39762 (601) 325-3432

MISSISSIPPI STATE UNIVERSITY
MISSISSIPPI STATE UNIVERSITY
MISSISSIPPI STATE, MS 39762

EXEMPTION DETAILS

1. Up to 97 mature beagle dogs are on projects studying the effects of antimicrobial compounds on periodontal disease progression. These studies involve the maintenance of a dog colony in which all dogs have various degrees of periodontal disease (no dogs seem in pain or distress, however, during the studies.) Various treatment are conducted on this animal model to effect a "cure," hoping that similar procedures could be used to treat periodontal disease in human beings.

   Beginning many years ago (around 1989), the investigator requested exemption from A.W.A. section 3.11(6) for these reasons:

   Both animal and human research protocols involving gingivitis and periodontitis are studies of a microbial driven disease process. Our studies of juvenile, middle aged, and geriatric patients (beagle dog colonies) are investigative studies of bacterial antigen, gingival attachment loss, increased soft tissue septic pocket depths, secondary bone loss, periodontal ligament necrosis and tooth loss. In addition, secondary systemic effects are triggered by an oral microbial response.

   Applying sanitizing chemicals (or 180°F water) to runs coupled with the self-grooming nature of dogs (licking chemicals off feet, etc.) alters this essential floor and/or oral microflora. Please be aware that each of these runs is extremely clean and is scrubbed and rinsed daily using detergent and hot water. These cleaning methods are the same as you would use on your household eating utensils. In summary, sanitation methods must be exempted from our protocols or all our models become invalid.

   The IACUC has discussed with every protocol alternative inoculation routes, use of hot (100°F) water only, increased health risks to dog, literature to support this premise, and other questions. Following considerable deliberations over several years, despite changing IACUC memberships, the committee has accepted the investigator's premise and has waived for this year of 2001 and for past projects the A.W.A. sanitation requirement. The studies continue to this date.

2. Since 1991 small swine housed in large, partitioned polypropylene tubs in Harned Hall, Arts and Sciences, have had an IACUC general approval (last approved August 15, 2000) to house 16 small pigs (47 over the 2000-2001 time period) in spaces per animal less than the 4-6 square foot per pig area specified in the ILAR Guide and in the AG Guide. The sheet attached shows, based on extrapolations from cat and rabbit cage sizes, how much space was deemed appropriate for each smaller weight category. No adverse effects of these smaller spaces for pair-housed young pigs have been noted over 10 years.

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 21

NOV 1 6 2004

See attached form for additional information.

Interagency Report Cont

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 65-R-0102

CUSTOMER NUMBER: 844

FORM APPROVED
OMB NO. 0579-0036

University Of Mississippi Medical Center
2500 N. State Street
Jackson, MS 39216

Telephone: (601) -984-1385

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

Guyton Building, Research Wing

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs			54		54
5. Cats	6		74		74
6. Guinea Pigs			0		0
7. Hamsters	63		167		167
8. Rabbits			43		43
9. Non-human Primates			88		88
10. Sheep			0		0
11. Pigs			72		72
12. Other Farm Animals					
13. Other Animals			0		0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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. OR INSTI OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/10/04

APHIS FORM 7023 (Replaces VS 3-23 (OCT 88), which is obsolete.)
(AUG 91)

University of Mississippi Medical Center
Program Exception Report

October 1, 2003 through September 30, 2004

Registration No: 65-R-0102
Customer No: 844

Exceptions to the exercise plan for dogs

A total of 31 dogs were housed in metabolic cages during the fiscal year. These animals are exempted from the canine exercise program. Metabolism dogs are chronically catheterized and continuously, consciously monitored via computer. The jacket system precludes large caging in order to minimize problems with the various instrumentation. The exemption from the exercise requirement has been approved by the University of Mississippi Medical Center's IACUC and verified by the LAF veterinary staff.

11-29-2001 RCVD

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **REGISTRATION NO.** 65-R-0102 **CUSTOMER NO.** 844

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
2500 N. STATE STREET
JACKSON, MS 39216

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)*

See Attached Listing

Arthur C. Guyton Laboratory Research Bldg.
8th Floor Research Wing

James D. Hardy Clinical Sciences Bldg.

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			107		107
5. Cats			6		6
6. Guinea Pigs			0		0
7. Hamsters			332		332
8. Rabbits		70	141		211
9. Non-Human Primates			79		79
10. Sheep			0		0
11. Pigs			134		134
12. Other Farm Animals					
13. Other Animals					
Ferrets	4		37		37

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/14/01

APHIS FORM 7023 (AUG 91)

aces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

University of Mississippi Medical Center
Program Exemption Report

October 1, 2000 through September 30, 2001

Registration No: 65-R-0102

Exceptions to the exercise plan for dogs

A total of 36 dogs were housed in metabolic cages during the fiscal year. These animals are exempted from the canine exercise program. Metabolism dogs are chronically catheterized and continuously, consciously monitored via computer. The jacket system precludes large caging in order to minimize problems with the various instrumentation. The exemption from the exercise requirement has been approved by the UMC IACUC and verified by the LAF veterinary staff.

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 21

See attached form for additional information.

Interagency Report Control No.: 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 71-R-0100
CUSTOMER NUMBER: 1408

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

A R Children's Hosp Res Inst
1120 S Marshall St
DEC 1
Little Rock, AR 72202

Telephone:
(501)320-2700

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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 NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			98		98
9. Non-human Primates					
0. Sheep					
1. Pigs		4	43		47
2. Other Farm Animals					
3. Other Animals					
Rats		580	952	15	1547
Mice		375	37		412

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, 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 s 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)

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

DATE SIGNED 11/17/00

APHIS FORM 70 (AUG 91)

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

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 73-R-0002 CUSTOMER NO. 8233

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

O K MED RES FOUNDATION
825 NE 13TH ST
OKLAHOMA CITY, OK 73104
(405) 271-7085

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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			19		19
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10.7.03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

OCT 10 2003

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 73-R-0002
Customer Number: 8233
Facility: O K MED RES FOUNDATION
825 NE 13TH ST
OKLAHOMA CITY, OK 73104
(405) 271-7085

SITE1
825 NE 13TH ST.
OKLAHOMA CITY, OK 73104

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 73-R-0030 | CUSTOMER NO. 1417 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, Include Zip Code)*

HAIR, J. ALEXANDER
320 N RANGE RD
STILLWATER, OK 74074
(405) 377-4132

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)*

See Attached Listing
320 N. Range Rd
Stillwater Okla 74074

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 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	13	144	0	0	157 (14)
5. Cats	17	0	0	0	17 (0)
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.

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, the 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
		06 Nov 03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 1[illegible]-23 (Oct 87), which is obsolete)

PART 1 - HEADQUARTERS

Must Submit by Nov

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 73-R-0100 CUSTOMER NO. 1450

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIV OF OKLAHOMA-NORMAN
633 ELM ST
NORMAN, OK 73019
(405) 325-2077

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	2	1			1
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Chipmunks	19	60			60

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 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 OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/10/03

APHIS FORM 7023 (AUG 91)

FORM 7023 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

NOV [illegible] 2003

Customer and ID Site Address:

ID: 1450

Animal Sites:

Dale Hall/Dale Hall Tower
455 W. Lindsey
Norman OK 73019

Zoology Animal Facility
1060 Asp
Norman OK 73019

Animal Holding Facility
1060 Asp Ave.
Norman OK 73019

Physical Sciences Building
601 Elm
Norman OK 73019

Felgar Hall
865 Asp Ave.
Room 130A
Norman OK 73019

George Lynn Cross Building
770 Van Vleet Oval
9th Floor
Norman OK 73019

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 73-R-0100
Customer Number: 1450
Facility: UNIV OF OKLAHOMA-NORMAN
633 ELM ST
NORMAN, OK 73019
(405) 325-2077

SITE1
633 ELM ST
NORMAN, OK 73109

UNIVERSITY OF OKLAHOMA
LAB ANIMAL RESOURCES
633 ELM STREET
NORMAN, OK 73019

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 73-R-0101 | CUSTOMER NO. 1439 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

FERRELL FARMS INC
30140 OKLAHOMA ST
MCLOUD, OK 74851
(405) 964-3710

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	10				
11. Pigs					
12. Other Farm Animals					
GOATS	10	15			15
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.

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 (or the appropriate authority) 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
		11-23-03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 7023 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

26 2005

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	73-R-0101
Customer Number:	1429
Facility:	FERRELL FARMS INC 30140 OKLAHOMA ST MCLOUD, OK 74851 (405) 964-3710

SITE1
30140 OKLAHOMA ST
MCLOUD, OK 74851

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 74-R-0011 CUSTOMER NO. 1382

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

ALCON RESEARCH, LTD
PO BOX 6600
ATTN: VP PRECLINICAL SCIENCES
FORT WORTH, TX 76115
(817) 293-0450

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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			18		18
6. Guinea Pigs		16	1,621	4	1,641
7. Hamsters					
8. Rabbits	406	1,456	4,281		5,737
9. Non-Human Primates	11		369		369
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/29/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

NOV 17 2003

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 74-R-0011
Customer Number: 1382
Facility: ALCON RESEARCH, LTD
PO BOX 6600
ATTN: VP PRECLINICAL SCIENCES
FORT WORTH, TX 76115
(817) 293-0450

Site 1
6201 South Freeway
Attn:
Fort Worth, TX 76134

Site 2
Dallas Veterans Affairs Medical Center
Attn:
4500 South Lancaster Rd
Dallas, TX 75216
Telephone:

NOV 17 2003

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number:** 74-R-0011

2. **Number** 4 **of animals used in this study.**

3. **Species (common name)** guinea pig **of animals used in the study.**

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

   Guinea pigs are injected with approximately 0.06% sodium hyaluronate, horse serum (positive control), or 0.9% saline (negative control), on three occasions into the peritoneal cavity. Subsequently, each test subject is injected intravenously and examined for anaphylactic response. Guinea pigs are humanely euthanized after the last regimen is completed. The 4 animals in Column E are positive controls and are expected to exhibit symptoms of respiratory distress, collapse, and death.

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).**

   The guinea pig is an established model for antigen-induced respiratory anaphylaxis. Anaphylaxis is the required outcome of the positive control for this study. No analgesic compounds were administered since they would potentially confound interpretation and conclusions from this study. This test was developed in response to required safety testing by the Japanese Ministry of Health and Welfare for marketing viscoelastic products in Japan.

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 Japanese Ministry of Health and Welfare

   CFR The Pharmacopoeia of Japan, 13th edition, 1996, page 322

This report is required by law (7 USC 21 43) Failure to report according to the regulations can result in an order to cease and desist and to be subject in penalties as provided for in Section 2150

See reverse side for additional information

Interagency Report Control No 0180-0OA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 74-R-0048 1514

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA Include Zip Code)

Southwest Texas State University
601 University Drive, JCK Suite 489
San Marcos, TX 78666

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

FACILITY LOCATIONS (Sites)

3a. Site1- 601 University Dr., San Marcos (main campus)
3b. Site 2 - University Farm, RR12, San Marcos

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	42	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	215 cows	0	0	0	0
	20 goats	0	0	0	0
13 Other Animals	4300	3176	5103	56	8335

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 CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		12/1/03

Which is obsolete

DEC 1 2003

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 2150

Set reverse side for additional information 1514

Interagency Report Control No 0150-BOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO 74-R-0048

FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA Include Zip Code)

Southwest Texas State University
601 University Drive
San Marcos TX 78666

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 — 12. &/OR 13. Other (List by species)	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)
bats	0	0	63	0	63
various mammals	0	10	0	0	10
birds	0	0	0	21 **	21
birds	0	0	40	0	40
fish	800	800	0	0	800
fish	30	80	0	0	80
fish	40	160	0	0	160
fish	200	0	0	0	0
fish	55	0	0	35 ***	35
fish, Xiphophorus	3100	1900	5000	0	10000
fish	50	150	0	0	150
fish	20	70	0	0	70
fish	0	6	0	0	6
salamanders	5	0	0	0	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, 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 2142).

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		12/1/03

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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, as registered with USDA, include Zip Code)*

STILLMEADOW INC
12852 PARK ONE DR
SUGAR LAND, TX 77478

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)*

SITE1
SUGAR LAND, TX 77478

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	158	531	8	24	563
5. Cats	49	155		24	179
6. Guinea Pigs		541		29	570
7. Hamsters		88		20	108
8. Rabbits		1200		140	1340
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Horses		2	11		13
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/21/2003

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

APR - 1 2004

74R0048
1514

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:

Dogs (24)
Guinea Pigs (29)
Cats (24)
Rabbits (140)

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 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

CFR:

Approval Status:
Approved/Disapproved By:
Date:

Disapproved Reason:

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 74-R-0050 CUSTOMER NO. 1481

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

TEXAS TECH UNIVERSITY H S C
3601 4TH ST
LUBBOCK, TX 79430
(806) 743-2565

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)*

See Attached Listing

3601 4th Street, Lubbock, TX 79430

4800 Alberta Dr., El Paso, TX 79905

1400 Wallace Blvd., Amarillo, TX 79105

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			36		
5. Cats			49		
6. Guinea Pigs					
7. Hamsters				100	
8. Rabbits		61	17		
9. Non-Human Primates			8		
10. Sheep					
11. Pigs			72		
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/8/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete Graduate School PART 1 - HEADQUARTERS

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 74-R-0500 , 1481

2. Number 100 of animals used in this study.

3. Species (common name) hamster of animals used in the study.

4. Explain the procedure producing pain and/or distress.
   Each hamster will be administered 30mg/kg of clindamycin by intragastric inoculation under ether anesthesia. A small - diameter, polyethylene tubing will be used for all intragastric inoculations. Twenty-four hours after clindamycin challenge each hamster is inoculated with one ml. of an overnight broth culture of C. difficile (approximately 10^5 bacteria/ml.) The animals will be observed at least every 8 hours for evidence of disease.

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)
   Only live animals can be used to demonstrate prevention of a disease development. analgesics cannot be administered because they will inhibit some of the pathology (e.g. inflamation) we are attempting to define in this animal model.

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 _____ CFR _____

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 21

additional information.

0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 74-R-0068
CUSTOMER NUMBER: 1454

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Health Science Center At Houston
University Of Texas
Po Box 20036

Telephone:

Houston, TX 77225

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

FACILITY LOCATIONS (Sites) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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 NUMBER OF ANIMALS (COLUMN C + D + E
4. Dogs	358	35	115		150
5. Cats					
6. Guinea Pigs				627	627
7. Hamsters					
8. Rabbits	259	30	727		757
9. Non-human Primates		34	73		107
0. Sheep					
1. Pigs			80		80
2. Other Farm Animals					
3. Other Animals					
Deer			7		7
Ferrets		9			9

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesteatic, 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)

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

DATE SIGNED 11/25

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

NOV 28 2003

74R0068
1454

COLUMN E

Registration Number: 74-R-0068
Number of Animals used in this study: 627
Species (common name) of animals used in the study: Guinea pigs
Purpose of study: The testing is done to find out whether a particular drug is good for a particular fungus infection. Fungus infections are a common complication of people and animals that have compromised immune systems such as people or animals that are on chemotherapy for cancer or people suffering from AIDS. Developing new drugs that can fight this infection is important for minimizing suffering and death from this potentially life-threatening disease.

The recognized standard measurement for this testing is to see whether the animals that received the drug live longer and to see whether fungus is cleared from their organs. The comparison is made between those animals that are given the infection with treatment and those animals that were given the infection without treatment.

Explain the procedure producing pain and/or distress: During the course of the testing (experiments), the animals will be made sick by giving them an injection of a particular fungus in their vein. The animals will be maintained in their normal environment and provided food and water. They will be monitored three times a day for signs of illness. This illness as it progresses can cause discomfort, much like the flu. The animals will be euthanized when it is apparent that they are not recovering from the infection. Signs include lack of appetite, inactivity, dull attitude. Animals that are treated with the anti- fungal drug may recover from the infection while those that are not treated or treated with less drug or with drug that is not good for this infection may suffer discomfort and pain prior to euthanasia. All efforts will be done to prevent excessive pain and suffering through very close and frequent observations to determine when euthanasia is needed.

74R0068
1454

Facility Locations (Sites) continued

Site 1	**University of Texas Medical School**
Site 2	**University of Texas Dental Branch**
Site 3	**University of Texas School of Public Health**
Site 6	**University of Texas Mental Science Institute**
Site 7	**Texas Department of Criminal Justice**
Site 8	**Memorial Hermann Hospital**

AT 11-25 APP R

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 74-R-0071 CUSTOMER NO. 1455

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF TEXAS
7703 FLOYD CURL DR
SAN ANTONIO, TX 78229
(210) 567-6166

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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 tranquillizing 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	2	19	79		98
5. Cats			10		10
6. Guinea Pigs				167	167
7. Hamsters	115	29		85	114
8. Rabbits	4	31	466		497
9. Non-Human Primates		145	27		172
10. Sheep					
11. Pigs		36	35		71
12. Other Farm Animals			54		54
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/17/20

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

PART 1 - HEADQUARTERS

NOV 21 2003

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	74-R-0071
Customer Number:	1455
Facility:	UNIVERSITY OF TEXAS 7703 FLOYD CURL DR SAN ANTONIO, TX 78229 (210) 567-6166

SITE1
7703 FLOYD CURL DR.
SAN ANTONIO, TX 78284

NOV 21 2003

30 Ocotober 2003

USDA Registration No. 74-R-071

The University of Texas Health Science Center at San Antonio
USDA Report 2002-03
Category "E"

Fifty nine (59) Guinea Pigs

Fifty-nine animals were used to test the efficacy of new anti-fungal agents against systemic Aspergillosis. The animals were challenged with the agent and then given different treatment regimes. They were included in Category E due to the potential of developing clinical signs of systemic Aspergillosis. Analgesics were not administered due to their ability to mask clinical signs and/or interfere with clinical observations. All animals were monitored daily and animals exhibiting severe clinical signs were euthanatized.

Twenty Six (26) Guinea Pigs

Twenty-six (26) guinea pigs were used in the development of a C*occidioides immitis* vaccine. The animals were challenged by the aerosol route after being inoculated with the vaccine candidates. Tissue samples were taken after euthanasia to test for pathogen load in the lungs and other tissues. The animals were monitored at least twice daily. Additional treatments were not administered due to their ability to mask clinical signs and interfere with respiration. Animals were euthanized at various timepoints to determine the validity of the guinea pig model for this disease. In this study, the animals did not show any obvious clinical signs of disease but did have organisms present in the lungs at necropsy.

Eighty two (82) Guinea Pigs

Eighty two (82) guinea pigs were used to study novel drug therapies for systemic *Cryptococcus neoformans*. The animals were challenged with the agent and then given different treatment regimes. They were included in Category E due to the potential of developing clinical signs of systemic Cryptococois. Analgesics were not administered due to their ability to mask clinical signs and/or interfere with clinical observations. All animals were monitored daily and animals exhibiting severe clinical signs were euthanatized.

Eighty Five (85) Hamsters

Eighty five (85) hamsters were used in aerosol tuberculosis studies designed to develop a better model of the human tuberculosis, and to study new vaccines and treatments for this disease. Additional treatments (i.e. analgesics) would lessen or mask the clinical symptoms and obscure the purpose of this study. Animals were included in Category E due to the potential of developing clinical signs of tuberculosis. All animals were monitored at least twice daily and any animals exhibiting pain or distress from the disease were euthanatized.

This report is required by law (? USC 21 43) 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 2150

Set reverse side for addition: information

Interagenc Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 74-R-0073
CUSTOMER NUMBER: 1469

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA Include Zip Code)
University of Texas
Medical Branch at Galveston
301 University Blvd.
Office of the VP for Research
Galveston, Texas 77550

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.)

FACILITYLOCATIONS (Sites)

See attached listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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, o 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 those 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	0	0	73	0	73
5. Cats	0	0	0	0	0
6. Guinea Pigs	21	5	144	342	491
7. Hamsters	2	14	408	439	861
8. Rabbits	182	60	317	0	377
9. Non-human Primates	0	0	1	8	9
10. Sheep	0	12	436	0	448
11., Pigs	0	122	66	0	188
12. Othe Farm Animals					
Goats	0	20	0	0	20
13 Other Animals Wood Rats		11			11
Cotton Rats	18		6		6
Gerbils	0	35	0	0	35
Peromyscus Mice	180	80	0	0	80

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 veterinarianfor 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 CEO OR	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		7/2/03

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88) which is obsolete
(AUG 91)

USDA Annual Report
74-R-0073

3. **Facility Location**

University of Texas Medical Branch – Galveston, Texas

USDA Annual Report
Column E Explanations
University of Texas Medical Branch
Galveston, Texas
74-R-0073

Guinea pigs – 12
The guinea pig is used as an animal model for the study of viral hemorrhagic fever. Variants of viral pathogens are compared with regard to virulence factors and pathogenesis of disease. LD_{50}/ID_{50} studies are used for comparison of attenuated vs. virulent variants. Analgesics would alter the measurements of parameters used (such as rectal temperature) to evaluate the animal's response to disease.

Hamsters – 172
Use of the hamster model to study virulence of different strains of yellow fever virus. This study investigates the molecular basis of the pathogenesis of disease. Since the virulence of some strains is unknown, death endpoints may be encountered until viral pathogenesis is established. When clinical signs of infection are established, moribund endpoints will be applicable.

Guinea pigs – 60
Use of the guinea pig model for study of vesiculoulcerative skin lesion caused by herpes simplex virus (HSV) complex, and evaluation of new treatment regiments. Since HSV is a neurotropic virus, pharmacologic agents that may alter the function of neuronal elements may not be used.

Nonhuman primates (Macaca sp.) – 4
Animal model of peripheral neuropathy. This study investigates the mechanisms of neuropathic pain through changes in gene expression and potential use as a therapeutic tool. Treatment with analgesics would alter the physiologic processes involved in pain sensation.

Nonhuman primates (Macaca sp.) - 4
Model for chronic inflammatory arthritis. Studies are designed to determine molecular, physiologic, and anatomic responses to inflammatory pain, and to develop interventions that will reduce or eliminate pain. Mild pain paradigms achieve experimental goals. Administration of opiate derivatives would interfere with analysis of acute and persistent pain mechanisms.

Hamsters – 51
This study examines the pathology of Hantavirus cardiopulmonary syndrome and as such, animals are given a lethal dose. Death is one of the outcome variables, and much of the pathology observed is related to the inflammation, thus ameliorating agents may alter outcome data.

Hamsters – 6
Infection of hamsters with phleboviruses. Analgesics may alter the disease process and invalidate the data. The disease is related to the inflammatory process and any agents that potentially alter that process can be expected to alter outcome data.

Guinea pigs – 168
Study of the pathogenesis of herpes simplex virus, a virus that resides within the nerves. Analgesics are suspected to alter the course of disease and thus unacceptable to the study. Reduction of inflammation would likely alter the outcome of the disease. Opioids would alter nerve conduction, which is a component of the study.

Guinea pigs – 82
The guinea pig is used as a model to study the pathogenesis of arenavirus hemorrhagic fever and to screen various drugs for treatment of the infection. Analgesics are contraindicated since the parameters used to study the course of infection in the animal could be affected.

Guinea pigs – 20
This is a study involving herpes simplex virus, which infects (resides) within the nerves. Analgesics could modify the metabolism within the nerves and thus are not permissible.

Hamsters – 192
Animal model for the study of flavivirus-induce encephalitis, sites of virus replication, mechanism of virus dissemination and neuroinvasion, and evaluation of efficacy of antivirals. LD_{50}/ID_{50} doses of the virus will be used for study of the pathogenesis of infection.

Hamsters – 18
Study of host immune response to infection with Leishmania organisms via footpad inoculation. Because molecular mechanisms of protective immunity and pathogenesis of disease are investigated, administration of any drugs that may interfere with normal inflammatory and/or immune response would be contraindicated.

USDA Annual Report
Exceptions to Housing Regulations
University of Texas Medical Branch
Galveston, Texas
74-R-0073

Four hundred and thirty-six (436) sheep were housed in metabolic stanchions for up to four weeks. They were housed in the stanchions for 48 hours prior to surgery to adapt them psychologically to this type of housing. The purpose of the stanchions was to prevent disruption of vascular catheters and other instruments placed surgically. These sheep have the most intensive care of any animals on campus with checks being at minimum four times daily (weekends, when there are actually few animals on study) to around the clock (during the week, depending on the study).

Eight (8) NHP (nonhuman primates) were housed singly in the same room. Pair housing was not permitted in order to prevent damage of longstanding indwelling scientific devices. There was concern that mutual grooming and other routine activities might dislodge delicate medical equipment. Physical contact (hands, etc.) was still possible through cage slats. Visual and vocal communication was also possible. These NHP's had daily contact with animal facility and/or research personnel. Environmental enrichment included the use of toys, puzzle feeders and food treats.

Four (4) dogs were pair housed in concrete runs for most of the year but there were four episodes of three weeks where each pair of dogs was housed singly in oversized cages. The cages were used during the period of time when the dogs were in contact with ticks carrying rickettsia. During this period of time, both ARC personnel and research personnel checked the dogs daily.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 74-R-0106 CUSTOMER NO. 9464

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

AMERICAN ANIMAL HEALTH INC.
2619 SKYWAY DRIVE
GRAND PRAIRIE, TX 75052
(972) 641-5420

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)*

See Attached Listing

See Attachment #1

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	5	4	0	0	4
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Cattle	0	8	0	68 See Attachment #2	76
13. Other Animals					
Goats	0	440	0	0	440

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10-06-03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

~~mailed 10/13/03 RF~~
Resubmission 10/24/03

OCT 27 2003

American Animal Health, Inc.
2619 Skyway Drive
Grand Prairie, TX 75052
U.S.Vet License 315

October 6, 2003

FACILITY LOCATIONS
Attachment #1

1.)	Burrer Testing Facility 2.0 Miles N. on the Hayden Ranch Rd. from the Junction of Tivydale Rd. Fredericksburg, TX 78624	Goats
2.)	Chester Spinrath Testing Facility Allerkamp Rd. Comfort, TX 78013	Goats
3.)	Farm Place Testing Facility 8.5 Miles S. & 0.4 Miles West/Junction of Wilson Creek Rd. & FM 1341 Comfort, TX 78013	Goats
4.)	Fredericksburg Texas Testing Facility Texas State Hwy 16 Fredericksburg, TX 78624	Cattle & Goats
5.)	Hillingdon Ranch Testing Facility 346 Giles Ranch Rd. Comfort, TX 78013	Goats
6.)	Johnson City Texas Testing Facility Rt. 1, Box 770 Johnson City, TX 78636	Goats
7.)	Laboratory Animal Testing and Storage Facility Building #3 2625 Skyway Drive Suite 102 Grand Prairie, TX 75052	Mice, Rabbits & Guinea Pigs

American Animal Health, Inc.
2619 Skyway Drive
Grand Prairie, TX 75052
U.S.Vet License 315

October 6, 2003

8.)	Squaw Creek Testing Facility 2.8 Miles South of Junction of Doss Rd. (FM648) and Squaw Creek Rd. Doss, TX 78618	Goats
9.)	Stieler Place Testing Facility 15 Miles S. on Hwy 87 from junction of Highway St. and Hwy 87 Comfort, TX 78018	Goats
10.)	White Oak Testing Facility 5 Miles S. of the Junction of Tivydale Rd. (FM 2093) & White Oak Rd. Fredericksburg, TX 78624	Goats

American Animal Health, Inc.
2619 Skyway Drive
Grand Prairie, TX 75052
U.S.Vet License 315

October 22, 2003

Attachment #2

The animals were used in the challenge protection tests conducted to demonstrate host animal immunogenicity for the licensing application of Mycoplasma Bovis Bacterin (Code 2760.00). Since this is a new product, the USDA still does not have a coded requirement in the 9CFR. These studies need to be in compliance with the Veterinary Services Memorandum Nos. 800.200 and 800.204 for acceptance as a host animal immunogenicity study.

For the test, 6-week-old susceptible animals were selected based on negative serological response and negative M. bovis isolation. The animals were randomly assigned to three groups: vaccinated, placebo, and non-vaccinated controls. Those vaccinated received two vaccinations at 2cc/dose by subcutaneous injection, 3 weeks apart. The placebo group was vaccinated in the same manner using only adjuvanted media. Two weeks after the 2nd vaccination, all vaccinated and placebo animals were challenged by Mycoplasma bovis field isolates to produce the disease. The non-vaccinated control group was not challenged.

After challenge, the animals were observed daily for clinical signs of the disease. Fourteen (14) days postchallenge, all animals in all groups were euthanized by captive bolt stunning followed by exsanguination and necropsy. Their lung lesions were evaluated and scored. A statistical analysis of the lung scores between vaccinates and the placebo group was conducted and reported to the USDA to fulfill the licensing requirements.

These tests invariably subjects animals to pain or distress by producing various degrees of clinical symptoms of pneumonia in order to simulate the actual protective effect of the vaccinated animal in comparison to that of the placebo animal. The 14 days post challenge waiting time is necessary in order to manifest pneumonic lesions if the animal is not protected. The pain or distress caused by the challenge to evoke the disease must not be treated as treatment may allay the disease but abolishes the condition demonstrating whether this bacterin can protect the animal from actual field conditions. The degrees of protection in the vaccinated animals are reflected in the severity of pneumonic lesions based on that of the placebo animals.

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 2150.

See reverse side for additional information.

Interagency Report Control Nr. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 74-R-0108 CUSTOMER NO. 1480

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

TEXAS TECH UNIVERSITY
P. O. BOX 42002
LUBBOCK, TX 79409
(806) 742-1160

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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		4			4
12. Other Farm Animals Goats		20			20
Cows		6			6
13. Other Animals					
Bats		11			11
Cottontail		12	2		14
Fox, Swift			19		19

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 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 C.E.O. OR INSTITUTIONAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/20/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

OCT 22 2003

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 74-R-0108 | CUSTOMER NO. 1480

FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

TEXAS TECH UNIVERSITY
P. O. BOX 42002
LUBBOCK, TX 79409
(806) 742-1160

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Gopher		3			3
Jackrabbit		2			2
Mouse, Deer	119	787			906
Mouse, Grasshopper		67	25		92
Mouse, Harvest		153	38	162	353
Mouse, Pocket		95	295		390
Mouse, Pygmy		42	5	90	137
Mouse, Texas		11			11
Mouse, White-footed		31	273	4	308
Raccoon		1			1
Rat, Cotton		84	226	73	383
Rat, Kangaroo		4	12		16
Rat, March Rice		120		203	323
Shrew		2		2	4
Squirrel, Ground		63	2	534	65
Vole, Prairie	103	140			243
Woodrat		3	151		154
	222	1117	1247		

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 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	INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
			10/20/03

APHIS FORM 7023A (AUG 91) (Replaces VS FORM 18-23 (, which is obsolete

PART 1 - HEADQUARTERS

OCT 22 2003

Additional Site Listings

LICENSEE/REGISTRANT NAME:	TEXAS TECH UNIVERSITY ACRC, Box 42002 Lubbock, TX 79409-2002
LICENSEE/REGISTRANT NO.	74-R-0108
CUSTOMER NUMBER:	1480
Phone	(806) 742-1160

SITE # 1 NAME OF SITE: Texas Tech University

ADDRESS: Biology Building, 6th Floor

Lubbock, TX County: Lubbock

CONTACT PERSON:

TELEPHONE:

SITE # 2 NAME OF SITE: Texas Tech University

ADDRESS: Human Sciences Building, Basement

Lubbock, TX County: Lubbock

CONTACT PERSON:

TELEPHONE:

SITE # 3 NAME OF SITE: Texas Tech University

ADDRESS: Northeast Lubbock County Field

Laboratories, Animal Science Facilities

Lubbock, TX County: Lubbock

CONTACT PERSON:

TELEPHONE:

SITE # 4 NAME OF SITE: Texas Tech University

ADDRESS: TIEHH

1207 Gilbert Drive, Bldg. 555 (Reese Center)

Lubbock, TX County: Lubbock

CONTACT PERSON:

TELEPHONE:

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 74-R-0108

2. Number 534 of animals used in this study.

3. Species (common name) Wild mice, wild rats and shrews of animals used in the study.

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

SEE ATTACHED

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)

SEE ATTACHED

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 N/A CFR N/A

Column E Explanation

1. Registration Number: 74-R-0108.

2. Number of animals used in this study: 534.

3. Species (common name) of animals used in the study:

Harvest mouse	162
Pygmy mouse	90
White-footed mouse	4
Cotton rat	73
Marsh rice rat	203
Shrew	2

4. Description/explanation/purpose of study: Protocol Title: Arthropods and Landscape Epidemiology
   - The purpose of this study is to understand the dynamics of (and correlations among) Hantavirus prevalence/ rodent population dynamics/ habitat changes/ parasitism within the native habitat, across spatial and temporal levels.
   - This is a "capture -mark-release-recapture" study conducted at Peach Point WMA, Freeport, TX (the study area is a marsh/swamp).
   - Hantavirus is a virus that causes mortality in 50% of human cases. Transmission of the virus is thought to occur by contact with rodents. Previous investigators identified Hantavirus in ectoparasites. This indicates that these ectoparasites may play an important role in the persistence and/or transmission of the virus in the natural habitat. This work is designed to determine the role of ectoparasites in Hantavirus transmission and to correlate this information with the landscape ecology (plant and habitat parameters) of a coastal habitat in Texas. Tissues of rodents and ectoparasites will be screened for the Hantavirus. Mark-recapture grids and standard survey sampling will provide data on the dynamics of Hantavirus infection in rodents, correlated with vegetation and habitat changes, and parasite data. Bayou Hantavirus is being studied in Texas in order to provide a more robust perspective on other data available, which has been collected primarily from Sin Nombre virus.
   - This study centers on wild-caught rodents that may be naturally infected with Bayou Hantavirus and ectoparasites in Texas. The Marsh rice rat is the target species for Hantavirus infection, but infection may occur in other species of rodents. The natural dynamics of the virus can only be successfully studied in the native habitat. Bayou Hantavirus has only been found in wild rodents and viral dynamics have not been approachable in laboratory studies.

5. Explain the procedure producing pain and/or distress:
   - Harvest mice, Pygmy mice, White-footed mice, Cotton and Marsh Rice rats, and Shrews were live-trapped using baited Sherman Live traps. The traps are set in an area of marsh/swamps with areas of standing waters. Traps were often modified to float in the marsh.

- 0.1 ml of blood was collected in the field (marsh/swamp) from the orbital sinus of live animals caught in Sherman Live traps, including Harvest mice, Pygmy mice, White-footed mice, Cotton and Marsh Rice rats and Shrews, using a sterile capillary tube. Animals were then released at the site of capture to minimize stress and maximize survival.

6. Provide scientific or regulatory justification for withholding of pain/distress relief: (Provide scientific justification why pain and/or distress could not be relieved. Clearly and scientifically justify why relieving pain or distress would unavoidably interfere with the purpose of the study in which the animals were used).
   - As in other studies of this nature, anesthesia was not administered, as it greatly increases handling time and decreases survival of the wild rodents.
   - There are no established doses/guidelines for the use of anesthetics/analgesics in the wild rodents involved in this study.
   - Marsh rice rats were released directly into the water following handling. Anesthesia is a liability in aquatic releases. Under such conditions, anesthesia would have increased the risk for drowning of rodents, and increased predation risk due to inherent initial lethargy during recovery.
   - Prolonged confinement following drug administration influences recovery and survival rates of wild-captured rodents. Recovery time can only be estimated, and determining appropriate drug dosage for trap-stressed animals can be problematic (Seal and Kreeger, 1987) and itself become a source of mortality.
   - "If pain is slight or momentary, it may be judicious not to use anesthesia so that the mammal can be released immediately." (*Guidelines for the Capture, Handling, and Care of Mammals - American Society of Mammalogists Animal Care and Use Committee*)
   - "The use of anesthesia for blood sampling will depend upon the procedure and species. Because some species are highly sensitive to anesthesia, the use of anesthesia should be weighed against the risk of mortality from the anesthesia." (*Guidelines for the Capture, Handling, and Care of Mammals - American Society of Mammalogists Animal Care and Use Committee*)

   State why blood must be collected:
   - To determine Hantavirus antibody status of the wild captured rodents.
   - Blood will provide temporal and spatial data on persistence of the Hantavirus in rodents as determined from serology (antibodies= evidence of viral past-exposure). These data document correlations among temporal and seasonal parameters for the Hantavirus antibodies/ rodent/habitat interactions.

   State why it must be circulating:
   - It is necessary to collect the blood from living rodents because the circulating blood must be collected with no possibility of contamination from non-vascular sources (e.g. organs, skin surface etc, as post-mortem collection would risk).
   - These animals are on a "mark recapture grid" and were released directly after the blood collection.

   State why blood pressure is important:
   - Anesthesia would lower blood pressure and make it difficult to collect a sample of blood.

State why animals could not be monitored during recovery from anesthesia:

- Prolonged confinement following drug administration influences recovery and survival rates of wild-captured rodents. Recovery time can only be estimated and determining appropriate drug dosage for trap-stressed animals can be problematic (Seal and Kreeger, 1987) and itself a source of mortality.
- Administration of anesthesia/analgesia increases handling time and reduces survival of the wild rodents.

State why reversible anesthetics could not be used:

- There are no established doses/guidelines for the use of anesthetics in wild rodents.
- As in other studies of this nature, anesthesia was not administered, as it greatly increases handling time and decreases survival.
- Under such conditions, anesthesia would have been a risk for drowning of rodents, and increased predation risk due to inherent initial lethargy during recovery.

State why etherization is used for euthanasia, rather than a safer and less stressful method:

- Animals to be euthanized were transported from the swamp/marsh area of capture to the field lab, then euthanized, and ectoparasites and organs were collected for Hantavirus PCR and serology analyses.
- The 2000 Report of the AVMA Panel on Euthanasia Appendix 3 states "ether is conditionally acceptable for rodents and small mammals".
- Ether also anesthetizes the ectoparasites, which are collected from euthanized animals.

State methods or means used to determine that pain and/or distress relief would interfere with test results:

- Administration of drugs that provide pain and/or distress relief would be an additional procedure that could increase handling time and stress to the animal and affect the survival of the wild rodents.

State that the pain or distress, which occurred, was, in fact, the minimum necessary to achieve the study's objective.

- 0.1 ml of blood (minimum amount necessary for serology) was collected in the field as efficiently as possible with the minimum amount of stress to the wild capture rodents.
- Distress due to handling and blood collection was minimized by swift application of the blood collection procedures. Unpublished data strongly suggest that there is no adverse response to these blood collection procedures.
- Immediately after the blood collection the animals were released at the exact site of capture to enhance orientation to their home environment and thus maximize survival.

Optional Column E Explanation Form

Protocol :
Title: Arthropods and Landscape Epidemiology

4.
Wild mice, wild rats and shrews in the field had blood collected from the orbit using a sterile capillary tube.

5.
This procedure requires that the blood be circulating and that the blood pressure not be affected by anesthesia. Administration of an analgesic in the mark-recapture animals would be an additional procedure that could add additional handling time and stress to the animal. Marsh rice rats often are released directly into the water (at site of capture), following handling. Anesthesia would be a liability in such releases, as there would be a risk for drowning, and in any case there is an increased predation risk due to inherent initial lethargy during recovery. For other species, confinement in traps for some time influences recovery and survival rates following drug administration. Since confinement time can only be estimated, determining appropriate drug dosage for trap-stressed animals can be problematic (Seal and Kreeger, 1987) and itself a source of mortality.

Distress due to handling and blood collection are minimized by swift application of procedures. Moreover, unpublished data strongly suggest that there is no adverse response to these handling procedures. Any captured animal that is injured or is lethargic and appears unlikely to recover will be euthanized by etherization.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 74-R-0159 CUSTOMER NO. 1718

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF INCARNATE WORD
4301 BROADWAY
SAN ANTONIO, TX 78209
(210) 829-3152

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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					
wood rats				148	148

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 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 L OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/26/03

, which is obsolete

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 74-R-0159
Customer Number: 1718
Facility: UNIVERSITY OF INCARNATE WORD
4301 BROADWAY
SAN ANTONIO, TX 78209
(210) 829-3152

DR. L. AGNESE, JR./UNIVERSITY OF INCARNATE WORD
4301 BROADWAY
SAN ANTONIO, TX 78209

DEC 7 200

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 74-R-0159

2. Number 148 of animals used in this study.

3. Species (common name) Wood Rat of animals used in the study.

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

The wood rats are captured, restrained, and sampled by ear puncture for LEISHMANIA. They are then released.

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)

The pain is minimal, and use of anaesthetic would render the animals more susceptible to predation. This was discussed and approved by the UIW IACUC in May, 1998.

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 None CFR

10/22/03

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

CORIXA MONTANA

1. REGISTRATION NO. ~~81-R-0035~~ 81-R-011 | CUSTOMER NO. 10011 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, Include Zip Code)

CORIXA CORPORATION
1124 COLUMBIA STREET, SUITE 200
SEATTLE, WA 98104
(408) 363-6214

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.)

81-R-0011

FACILITY LOCATIONS (sites)

See Attached Listing CORIXA MONTANA

1st OCT — 30th SEPT 2003

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	8	559			559
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		10/22/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

OCT 24 2003

12-203 Laris

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. **REGISTRATION NO.** 82-R-0002 **CUSTOMER NO.** 1079

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*

REGENTS OF THE UNIV. OF IDAHO
P O BOX 443010
MOSCOW, ID 83844
(208) 885-8958

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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					-0-
5. Cats					-0-
6. Guinea Pigs					-0-
7. Hamsters					-0-
8. Rabbits		9		2	11
9. Non-Human Primates					-0-
10. Sheep			5		5
11. Pigs					-0-
12. Other Farm Animals					
13. Other Animals					
Deer mouse		6			6
Wild mouse		38			38
Bighorn Sheep	26	3			3

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/24/03

APHIS FORM 7023 **(AUG 91)** **(Replaces VS FORM 18-23 (Oct 88), which is obsolete** **PART 1 - HEADQUARTERS**

NOV 26 200

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 82-R-0002 CUSTOMER NO. 1079

FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

REGENTS OF THE UNIV. OF IDAHO
P O BOX 443010
MOSCOW, ID 83844
(208) 885-8958

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
North American Elk	37	31			31
Bison	26	11			11
Pygmy Rabbit		86			86
Fox Squirrels		14			14

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/24/03

APHIS FORM 7023A (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

NOV 26 2003

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 82-R-0002
Customer Number: 1079
Facility: REGENTS OF THE UNIV. OF IDAHO
P O BOX 443010
MOSCOW, ID 83844
(208) 885-8958

REGENTS OF THE UNIV. OF IDAHO
UNIVERSITY OF IDAHO
MOSCOW, ID 83844

UNIVERSITY OF IDAHO
2696 GLEASON MCABEE ROAD
PRIEST RIVER, ID 99999

11-12-02

no longer in use
please drop

REGENTS OF IDAHO OF THE UNIVERSITY OF IDAHO
REGENTS OF IDAHO/UNIV. OF IDAHO
CALDWELL, ID 83844

NOV 26 2003

Column E Explanation

1. Registration Number: 82-R-0002
2. Number of animals used in this study: 2
3. Species (common name) of animals used in the study: Rabbit
4. Explain the procedure producing pain and/or distress.

   Young adults of either sex are used for toxicity experiments. The minimum number of animals are used that will give interpretable results. Generally, this is two per toxin. If both of the two animals exhibit the same reaction, generally positive or negative, we do not test further. However, in some cases where the results are not conclusive, we may need to use additional animals, generally groups of three. In some toxicity tests, the toxins are injected IV, in others they are slowly released from subcutaneous (surgically-implanted) osmotic pumps.

   Clinical effects of toxins used include fever, lethargy, and mortality, with mortality being the key indicator of toxin severity. Although not 100% accurate, previous study results have indicated loss of righting reflex is a good indicator of impending mortality and is thus used as the endpoint of the experiment.

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)

   Although the mechanisms involved in induction for staphylococcal food poisoning and toxic shock syndrome are currently not completely understood, it is known that the events leading to these diseases are multifactorial and complex. Thus, no tissue culture or cell technique that represents the ability of the toxins to cause either of these human diseases is known. It is our long-term goal to promote both human and animal well-being through this research. To achieve this goal, it is essential that we obtain an in depth knowledge of the structural and functional organization of these bacterial toxins. The morbidity and mortality associated with toxigenic staphylococcal and streptococcal diseases is significant for both humans and other animals. For example, toxic shock syndrome and the newly described "flesh eating" streptococcal disease fall into this category. Furthermore, diseases of domestic farm animals such as mastitis are highly associated enterotoxin-producing staphylococci. It is likely that the toxins modify the immune response in animals, as in humans, allowing the organism to persist and cause infection. This research will help us identify the regions of toxin molecules and then to test potential vaccine candidates possessing these regions in animals to determine if they induce protection.

   Antibodies are used to purify toxins from staphylococcal cultures and also check for structural changes caused by any mutation that we introduce in the protein molecules. Rabbits are used for toxicity testing. They are the best model for human toxic shock syndrome, another illness caused by the toxins studied in this project. It is hoped that these studies will provide some insight into the molecular and cellular mechanisms of action of this group of toxins and lead to the development of systems that allow us to continue similar studies without animals.

   The only effective means of preventing distress associated with the toxicological process would be to suppress the shock response, inhibiting the ability to determine if the toxin is clinically active and thereby negating the purpose of the experiment. Therefore, animals are not administered analgesics, tranquilizers, or other medical therapies to combat toxin effects. Instead, when loss of righting reflex occurs animals are euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific secion number (e.g., APHIS, 9 CFR 113.102)

   Agency: _____ CFR: _____

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES 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. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

INHAUSEN RESEARCH INSTITUTE, INC.
PMB 505/2601 S. LEMAY AVE.,SUITE 7
FORT COLLINS, CO 80525
(970) 221-1090

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)*

See Attached Listing
2625 Midpoint Dr., Ft. Collins, CO 80525

2619 Midpoint Dr., Ft. Collins, CO 80525

2637 Midpoint Dr, Ft. Collins, CO 80525

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	48	230	34	54	318
5. Cats	0	45	0	0	45
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	116	0	0	116
8. Rabbits	0	108	6	0	114
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	3	0	3
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	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, 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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10-29-03

APHIS (AU (Replaces VS 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

OCT 30 2003

Column E Explanation

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.

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 1273 84-R-0051

FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Genesis Laboratories, Inc.
10122 N.E. Frontage Rd.
Wellington, CO 80549 970-568-7059

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12. &/OR 13. Other *(List by species)*	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)
Northern Pocket Gopher	0	16	0	0	16
Gray Squirrel	0	17	0	0	17
Rock Squirrel	44	0	0	0	44 OK 12/10
Black-Tailed Prairie Dog	0	20	0	0	20
White-Footed Mouse	2	0	0	50	50
Nutria	0	24	0	0	24

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
	NOV 30 2004	11-29-04

APHIS FORM 7023A
(AUG 91)

PART 1 - HEADQUARTERS

ANNUAL REPORT OF ANIMALS USED BY GENESIS LABORATORIES, INC.
DURING THE 12 MONTH PERIOD OCTOBER 1, 2003 TO SEPTEMBER 30, 2004

HEADQUARTERS OF RESEARCH FACILITY	FACILITY LOCATIONS
GENESIS LABORATORIES, INC. 10122 N. E. FRONTAGE ROAD WELLINGTON, COLORADO 80549 Registration # 84-R-051	GENESIS LABORATORIES, INC. 10122 N. E. FRONTAGE ROAD WELLINGTON, COLORADO 80549 Registration #: 84-R-051

ANIMALS REPORTED IN COLUMN E

Wild Norway Rat (*Rattus norvegicus*)

Ninety-three (93) rats used are being reported in column E of the Annual Report. All animals used were used in studies testing rodenticides. USEPA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Pesticide Assessment Guideline Subdivision G, Section 96-10, Commensal Rodents, was followed during these procedures. FIFRA mandates that efficacy data be generated to support label claims for rodent control. No anesthetics, analgesics, or tranquilizing drugs were used to relieve the pain. Animals displaying toxicosis were not euthanized. The USEPA policy on rodenticide testing (Attachment 1) forbids the use of pain-relieving drugs and premature euthanasia. Use of such drugs or procedures would negate the study. There are no alternatives available to this painful procedure. The only alternative to administration of a toxic product (which is intended to kill animals, and cause unavoidable pain in that process) is not to administer the toxic product. Poisonous substances cause tissue damage, which results in pain perception. One potential alternative is to develop products which create unconsciousness or analgesia prior to death. However, information is not yet available to design such products, which would be effective for rodent control.

White-footed Mice (*Peromyscus leucopus*)

Fifty (50) mice used are being reported in column E of the Annual Report. The mice were used in studies testing systemic insecticides. USEPA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Pesticide Assessment Guideline 1.216 was adapted for this novel study. FIFRA mandates that efficacy data be generated to support label claims for products intended for public health applications. In these studies, which were designed to find the minimum effective dose which would kill ecto-parasites without harming the host (mouse), 28 animals died. The rest survived with no apparent pain or distress. For these product efficacy studies, no anesthetics, analgesics, or tranquilizing drugs were used to relieve pain. Animals were not euthanized. The USEPA policy on pesticide testing (Attachment 1) forbids the use of pain-relieving drugs and premature euthanasia. Use of such drugs or procedures would negate the study. There are no alternatives available to this painful procedure.

ATTACHMENT 1

The following is an e-mail response from Dr. William Jacobs of the USEPA, explaining his agencies position on the use of pain-relieving drugs or premature euthanasia in pesticide efficacy studies involving rodents. The e-mail was in response to a request by John Baroch at Genesis Laboratories, to state in writing and clarify the agency policy. Genesis Laboratories had been asked by APHIS, in 2004, to provide more detailed information on why pain relievers were withheld and why death was used as an endpoint in pesticide efficacy studies.

July 6, 2004:

"The issue of euthanasia was not mentioned in the "current" version of the [Pesticide Assessment] *Guidelines because it had not come into play with respect to efficacy testing protocols at that time. The Animal Welfare Act had been passed in the early 1970's, but there was common understanding that it was not to intrude upon the integrity of research. In efficacy studies involving toxicants, there must be a yes-or-no answer as to whether the poison killed the animal.*

The first instance that I remember encountering an efficacy protocol in which euthanasia was proposed happened in 1988. In that particular case, it appeared that the researchers were so intent on addressing euthanasia that they completely forgot what the research was about. In the course of reviewing that protocol, I drafted a response the gist of which was that the nature of the research was such that it was absolutely necessary to determine whether the poison killed the animal, that animals that recovered from having been poisoned with the rodenticide in question were not only likely to be the founders of the rebounding population but also would be behaviorally resistant (i.e., bait shy) to any bait containing the compound used in the initial trial. (The compound in question was an acute rodenticide.) Those are extremely important things to know about a rodenticide. I may have added that evidence indicating that a rodenticide routinely causes suffering should be considered in determining its suitability for future research and use.

I currently am revising the Guidelines and plan to address the issue of euthanasia much as I did in 1988, adding only that it would be permissible to euthanize seemingly moribund animals if not only the event of poison-caused death but also the time to death could be predicted with virtual certainty. This is a very tricky area, however. If we were to register a rodenticide based upon the results of laboratory and field trials in which eager-to-please personnel collected and dispatched every target rodent that they could get their hands on as soon as the animals appeared to be affected to any degree, we might wind up with a real turkey of a rodenticide on the market. A circumstance

not quite so extreme but certainly affecting some of the results that were reported occurred a while back and was only discovered when one researcher decided to collect symptomatic animals and cage them to see whether they would recover or die. Many of them recovered. Ultimately, it was determined that the active ingredient concentration needed in baits was double that which was used in the original field testing.

If I received a report of a laboratory efficacy trial in which it were stated that animals were "humanely dispatched", I would reject the study flat out. Percent mortality is the dependent variable in those trials. Adding additional causes of mortality would render the study useless as efficacy research.

In the case of the Genesis ground squirrel field trials to which you alluded, it seemed to me that field personnel may have been too eager to euthanatize animals. I recall a line in the report that said, in effect, that personnel dispatched every squirrel that they could catch but some "were able to slip down their burrows" (approximate quote) before they could be caught. Animals capable of slipping "down their burrows" would not seem to be moribund by anyone's definition, and I recall having responded to that.

If it is decided that a candidate rodenticide causes so much pain that it should not be considered for further use, then animals on test should be euthanatized and the results should be written up, not so much as an efficacy study, but as research aborted for humane reasons. Apart from that, I see no proper role for analgesics in rodenticide research. Rodenticide efficacy trials basically are behavioral studies. The effects of the candidate compound must be assessed isolated from other factors which might distort the observations and, of course, the animal's viability and ability to make adaptive responses -- such as slipping down a burrow. There is no way to sensibly use analgesics in field trials of rodenticide baits that would not be likely to interfere with behavior and viability. Even if the animals die after they "slip down their burrows", it is important that they are able to as where they die affects the determination of percent surface kill and the degree to which carcasses are available to nonfossorial scavengers and predators (such as avian raptors).

When we attempt to impose human values on animals' circumstances, we risk deluding ourselves. In general, wild animals are all about survival and will do whatever it takes (even chewing off their own feet) to last as long as they can. (Tranquilizer tabs associated with leg-hold traps turned out to be a good idea because some animals were spared further, self-inflicted, injuries on top of what the traps did to them. That, however, is a really exceptional case; and one which does not involve a vertebrate pesticide.) There also has been some

discussion of whether what appears to be distress is consciously perceived by the animal. Some of the older rodenticides produce symptoms which clearly look like distress, although humans exposed to the same compounds sometimes had little recollection of the experience. Some have suggested that anticoagulants, with their protracted times to death, "must" be inhumane. However, some humans who have bled severely internally (for one reason or another) have reported little or no discomfort and sought help only because of other symptoms (e.g., lethargy, evidence of occult blood, loss of function, etc.)."

result in an order to cease and desist and to be subject to penalties as provided for in Section 21

additional information.

12-5-04

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 84-R-0051
CUSTOMER NUMBER: 1273

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Genesis Laboratories, Inc.
10122 N.E. Frontage Road
Wellington, CO 80549

Telephone: (970) -568-7059

"A" by R. Rudenick
11/14/05

COPY FOR YOUR INFORMATION

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	0	95	0	0	95
7. Hamsters					
8. Rabbits	0	0	10	0	10
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Wild Norway Rat	50	0	0	93	93
Wild House Mouse	0	0	46	0	46
Plains Pocket Gopher	0	16	0	0	16

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 app 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 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 & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-29-04

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

NOV 30 2004

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 84-R-0059 **CUSTOMER NO.** 1834

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF COLORADO (HSC)
4200 E. 9TH AVENUE, BOX A-095
DENVER, CO 80262
(303) 724-1057

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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			14		14
5. Cats					
6. Guinea Pigs		3	108		111
7. Hamsters					
8. Rabbits		33	59	6	98
9. Non-Human Primates	34		18	5	23
10. Sheep			147	23	170
11. Pigs			74	3	77
12. Other Farm Animals					
Goats			4		4
13. Other Animals					
Gerbils		4			4

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/25/03

FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 84-R-0059
Customer Number: 1834
Facility: UNIVERSITY OF COLORADO (HSC)
4200 E. 9TH AVENUE, BOX A-095
DENVER, CO 80262
(303) 724-1057

UNIVERSITY OF COLORADO (HSC)
4200 E. 9TH AVE.
DENVER, CO 80220

CATEGORY E STUDIES

1. Sheep exposed to heat stress - 23 sheep

Description of Procedures:

Pregnant sheep are placed in an environmental chamber that cycles room temperature between 40-40.5 °C for 12-14 hours/day and 35 °C for the remainder of the day from day 33-35 of gestation until day 90-115. Humidity in the chamber is 45-50%. Animals are housed in standard cages with ad lib water and food. For safety, the heating system is equipped with an alarm and automatic cut-off system.

Explanation of Reasons Why Pain- or Distress- Reliving Drugs Were Not Used:

The procedure is designed to mimic a naturally occurring phenomenon, namely, pregnancy in hot climates where fetal intrauterine growth retardation is a common problem. The animals in the chamber under these conditions give no visual or clinical indication of stress. They eat and drink normally; their stool pattern is also normal; and their wool continues to grow. The procedure does alter placental development, but since altered placental development is not known to be associated with pain or distress in any species, use of any drug or other treatments would be speculative and possibly problematic for fetal development.

2. Rabbits exposed to bacteria infection - 6 rabbits

Description of Procedures:

This is a study of the effects of exposure to bacteria during the birth process. The goal of the protocol is to determine, after intra-cervical inoculation of pregnant rabbits with E. coli, G. vaginalis or B. bivius and treatment with antibiotics, the extent of tissue damage over time and whether therapeutic intervention with IL-1a reduces fetal injury. Timed pregnant rabbits at 70% gestational age are anesthetized and inoculated intra-cervically with 10^3 to 10^4 CFU E. coli, G. vaginalis or B. bivius. Some animals are treated with ampicillin sulbactam. At 1 to 7 days after inoculation, the animals are euthanized and the tissues evaluated. In another group, rabbits are given IL-1ra or saline each day (iv; ear vein) for 5 hours each day. This study requires an iv drip for 5 hours/day, therefore restraint is needed for the constant infusion. After consultation with the University Veterinarian, a wire rabbit box without neck restraint was chosen. The rabbits are gradually acclimated to this restraint over a 5 day time period. At 1, 3 and 5 days, animal are euthanized and the tissues evaluated.

Explanation of Reasons Why Pain- or Distress- Reliving Drugs Were Not Used:

It is important to understand the risk of maternal and newborn infection. It is therefore necessary to allow the experiment to continue until it can be determined whether or not the does and neonatal rabbits become infected by exposure to bacteria during the birth process. Antibiotics and IL-1ra treatment given to mothers before delivery may be an effective treatment. The difference in outcome of animals given IL-1ra and those not treated is the focus of these studies. Drugs given to relieve any possible distress would mask the degree of infection and interfere with the immunoassays to be done, therefore none are given.

3. Food restriction in pigs – 3 pigs

Description of Procedures:

The goal of the protocol is to provide hands on training for Board Certified Gastroenterologists and Gastroenterology Nurses in the technique of endoluminal gastroplication, a gastral endoscopic suturing technique. The pigs are placed on a pre-procedural food restriction for 48 hours where they are fed Jell-O on day one and honey/water on day 2. The pigs are then anesthetized and the endoluminal gastroplication performed. The animals are euthanized by an anesthetic overdose at the end of the non-survival surgery.

Explanation of Reasons Why Pain- or Distress- Reliving Drugs Were Not Used:

Due to the highly technical nature of the endoluminal gastroplication procedure, proper training of Physicians and Nurses is required for optimal safety and efficacy of performing this procedure on human patients. The full 48 hour food restriction as described above is required to ensure that the stomach is completely clean for ease of visualization by the Physicians and Nurses learning the procedure. The procedure, endoluminal gastroplication, requires careful examination of the internal mucosal lining of the stomach. Thus, even a small amount of residual material inside the stomach is unacceptable because it interferes with proper visualization, and thereby impairs the trainee's ability to learn how to perform this procedure. Alternative procedures to clean out the digestive tract are not acceptable since the mucosal lining becomes bloody, thereby decreasing visualization.

4. Parkinsonian Syndrome in non-human primates - 5 monkeys (M. radiata)

Description of Procedures:

The Parkinsonian syndrome is induced when MPTP-HCL is infused into the carotid artery to produce a stable unilateral lesion in the monkey. A dose of 0.8 mg/kg MPTP-HCL dissolved in 50 cc of sterile normal saline infused into the carotid artery over

20 minutes leads to unilateral dilation of the pupil and a weak arm and leg contralateral to the side of the lesion and sensory neglect on that side. The animals are infused at a rate of 2 ml/minute using a 30 gauge needle with the infusion in the direction opposite the normal arterial blood flow. Analgesics are given to all animals for any post-operative pain. The result of the surgical procedure is a weak arm and leg and sensory neglect on the side opposite the lesion. (Water bottles are adjusted for this disability.) Thus, once monkeys have been lesioned, abilities such as locomotion, visual fields, grasping, climbing, etc. are impaired. In addition, the lesioned animals are sensitive to sound and have an enhanced startle response. After the lesioning procedure has produced the hemi-parkinsonian effect, each animal is assessed daily for any pain. L-dopa is given as needed to assist the animal in daily routine procedures. In addition, monkey's food intake is carefully assessed and animals are hand fed if necessary until they have learned to adapt to their limitations. Daily fruit, sunflower seed, pomegranate seeds, peanuts, etc., are provided to occupy their foraging behavior. The post lesion state lasts about six to eight months. As the animals become more adept with their routine movements, more foraging materials and additional toys are introduced.

Explanation of Reasons Why Pain- or Distress- Reliving Drugs Were Not Used:

To study the effective treatment of Parkinson's disease, an animal model of the disease is essential. There are currently no effective long-term treatments for this disease and therefore no way to completely eliminate the distress that may be associated with the physical limitations imposed by this disease. It is the goal of this study to test a treatment that may effectively cure the monkeys and, ultimately, human beings.

EXCEPTIONS TO REGULATIONS

The IACUC has approved an exception to the policy regarding multiple surgeries, specifically the placement of maternal and fetal catheters in sheep. The goal of the protocol is to determine how fetal glucose, amino acid and plasma insulin availability regulate fetal energy and amino acid metabolism and thereby lead to changes in fetal growth. For the 2-3 week chronic studies, an initial surgery is done to catheterize the mother's femoral artery and vein. The catheters allow the Investigators to produce, by IV infusion, the necessary metabolic conditions (e.g. insulin-induced hypoglycemia; glucose induced hyperglycemia) and for arterial blood sampling. The fetus is too small to catheterize at this time, and maintaining patency of fetal catheters for more than 2 weeks is very difficult. Thus, a second surgery to place uterine and fetal catheters is done when the fetus is big enough and close enough to final study. The fetal catheters are then used for infusions in both hyperglycemic and hypoglycemic studies and for blood sampling. Within the last reporting period, ninety-four sheep have had multiple surgeries for placement of maternal and fetal catheters.

The USDA Sector Supervisor has approved an exception to the policy regarding multiple survival surgeries, specifically multiple Cesarean sections in Bonnet monkeys (letter dated 6/29/94). There is currently a moratorium on the importation of Bonnet monkeys. Therefore, multiple surgeries will use the fewest possible number of a rare species. No multiple Cesarean sections were performed during this reporting period under this exception. Furthermore, no non-human primates received a Cesarean section in the past year.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN 12/18/2

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 85-R-0010 **CUSTOMER NO.** 1074

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

CANYON COLORADO EQUID SANCT.
P.O. BOX 60639
COLORADO SPGS, CO 80960
(719) 579-0707

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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					
Grevy's Zebra	0	88	1		89
Hartmann Zebra	0	204	30		234
Kulan	0	272	3		275

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 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)

L OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/24/03

obsolete

PART 1 - HEADQUARTERS

Faxed 11.24.03

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 85-R-0010 CUSTOMER NO. 1074

FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

CANYON COLORADO EQUID SANCT.
P.O. BOX 60639
COLORADO SPGS, CO 80960
(719) 579-0707

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Onager	0	21	5		26
Somali Wild Ass	0	4	0		4
Przewalski Horse	0	31	17		48
Kiang	0	2	0		2
Hartmann/Kulan Hybrid	0	5	0		5
Hartmann/Onager Hybrid	0	1	0		1
Przewalski/Kulan Hybrid	0	1	0		1

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/24/03

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

PART 1 - HEADQUARTERS

G 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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. **REGISTRATION NO.** 85-R-0014 **CUSTOMER NO.** 1076

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF NEW MEXICO
HEALTH SCIENCE CENTER, ANIMAL RESOURCE FACILITY
ALBUQUERQUE, NM 87131-5186

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)*

UNIVERSITY OF NEW MEXICO
ALBUQUERQUE, NM 87131

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			60		60
7. Hamsters					
8. Rabbits		39	2		41
9. Non-Human Primates					
10. Sheep					
11. Pigs		19	18		37
12. Other Farm Animals					
Ducks		129	1		130
13. Other Animals					
Gerbils			87		87
Gerbils			87		87

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		09/29/2003

12-12-01

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 86-R-0006 CUSTOMER NO. 1049

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

ST. JOSEPH HOSPITAL & MEDICAL CENTER
350 WEST THOMAS RD.
PHOENIX, AZ 85013
(602) 406-3000

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	0	57	0	57
5. Cats	8	4	61	0	65
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	9	0	43	0	43
9. Non-Human Primates	17	1	9	0	10
10. Sheep	0	0	0	0	0
11. Pigs	0	0	22	0	22
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

RECEIVED
NOV 28 2001
USDA, APHIS, VS
GRAND JUNCTION, CO

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/27/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	86-R-0006
Customer Number:	1049
Facility:	ST. JOSEPH HOSPITAL & MEDICAL CENTER 350 WEST THOMAS RD. PHOENIX, AZ 85013 (602) 406-3000

BARROW NEUROLOGICAL INSTITUTE
350 WEST THOMAS RD.
PHOENIX, AZ 85013

St. Joseph's Hospital and Medical Center
Barrow Neurological Institute
Phoenix, Arizona 85013
Registration No. 86-R-006
FY - 2001

IACUC-approved exceptions to regulations and standards.

Two exceptions to regulations were approved by the Institutional Animal Care and Use Committee at St. Joseph's Hospital.

The first exception is the schedule for providing food to cats. As part of three IACUC-approved protocols that involve behavioral experiments, the provision of food to cats is restricted to one session each day in the laboratory. Food is provided as a positive reinforcement to obtain the behavior under study. At the end of each session, the animals are allowed to eat to satiation. Ten animals have been used in these protocols during the current reporting period.

The second exception is the schedule for providing water to rhesus monkeys. As part of an IACUC-approved protocol that involves behavioral experiments, the provision of water to rhesus monkeys is restricted to one session each day in the laboratory. Water is provided as a positive reinforcement to obtain the behavior under study. At the end of each session, the animals are allowed to drink to satiation. One animal has been used in this protocol during the current reporting period.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 86-R-0031
CUSTOMER NUMBER: 1698

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Sun Health Research Institute
10515 W. Sante Fe Dr.
Sun City, AZ 85351

Telephone: (623) -876-5328

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this repor	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits	12	84	54	16	154
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 anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 app 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 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 *(Type or Print)*	DATE SIGNED
		11/23/04

APHIS FORM 7023 (Replaces VS FORM (OCT 88), which is obsolete.)
(AUG 91)

NOV 29 2004

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 91-R-0006 **CUSTOMER NO.** 1018

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

BATTELLE MEM. INST., RICHLAND SITE
P. O. BOX 999, (MSIN P7-52)
RICHLAND, WA 99352

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)*

BATTELLE MEM. INST., RICHLAND SITE
RICHLAND, WA 99352

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	12				
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Bushytail Woodrat				1	1
Deer Mouse				45	45
GB Pocket Mouse				16	16

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/24/2003

APHIS FORM 7023 **(AUG 91)** (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 91-R-0006 **CUSTOMER NO.** 1018

FORM APPROVED
OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

BATTELLE MEM. INST., RICHLAND SITE
P. O. BOX 999, (MSIN P7-52)
RICHLAND, WA 99352

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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)
Mountain Cottontail				7	7
West. Harvest Mouse				3	3
Mule Deer				2	2

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/24/2003

APHIS FORM 7023A (AUG 91)

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

PART 1 - HEADQUARTERS

1. Registration Number: 91-R-0006 / 1018

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

Bushytail Woodrat (1)
GB Pocket Mouse (16)
West. Harvest Mouse (3)
Deer Mouse (45)
Mountain Cottontail (7)
Mule Deer (2)

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

All animals were collected under permit with Washington State Department of Fish and Wildlife as part of the Hanford Site Environmental Surveillance Program. These animals are collected to assess potential ecological effects of Hanford Site operations. Rodents and rabbits are collected with live traps (Sherman or Have-a-Heart traps). The bushytail woodrat was inadvertently trapped and released. Both trapping and handling of the woodrat before release was distressful. The deer mice (45 total) were both euthanized (n = 32) and trapped and released (n = 13). Sacrificed deer mice were euthanized by cervical dislocation. Both trapping and handling of mice before euthanasia is distressful to the animals. The Great Basin pocket mice were trapped and euthanized (cervical dislocation) for contaminant analysis. Both trapping and handling of mice before euthanasia is distressful to the animals. The cottontail rabbits were trapped and euthanized with a shot (22 cal. bird shot) behind the ear. Trapping of cottontails is distressful, both when the animal is initially trapped and when field technicians arrive to sample the animal. Euthanasia by shooting the animals while in the trap minimizes distress and provides a rapid and precise method of euthanasia. Other methods of euthanasia (penetrating captive bolt, administration of bartibuates, decapitation) require additional handling of the animals that increases distress. Shooting the animals while in the trap reduces handling stress, is quicker that other methods results (thereby reducing the time the animal is distressed), is quick (practically instantaneous) and minimizes pain. The western harvest mouse were trapped and euthanized (cervical dislocation) for contaminant analysis. Both trapping and handling of mice before euthanasia is distressful to the animals. The mule deer were shot and the animals likely experienced some pain and distress prior to death and sample tissue collection. Deer were shot and dispatched as quickly as possible by a shot to the head if necessary. Ninety-five percent of the time, deer are quickly dispatched with a single shot and pain and distress is minimized. The use of tranquilizers was considered and has been used in the pass for studies where deer were not sacrificed. There is an associated risk of the animals injuring themselves before the tranquilizer takes hold or of the animals entering the Columbia River and drowning. Tranquilized deer remain conscious longer than deer dispatched by gun and may experience more fear and stress before the tranquilizing drugs take effect than if shot by gun. Tranquilizing deer with dart guns is ineffective from the ground because it is difficult to get within range for an accurate shot in the open terrain at Hanford. Shooting from helicopters exposes sample collection staff to unnecessary risk of an accident and adds additional stress to the deer during the activity as they run from the helicopter as well as stressing other deer that may be present. Hunting is only done if the deer samples identified for the sample year can not be obtained from road kills. Overall, additional steps to apply pre-sampling anesthesia prior to either 1) the collection of field data or 2) sacrificing the animals for contaminant analysis would create more stress to the animals than the methods presently used.

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)

These are field collected samples of wildlife to measure potential ecological impacts of operations at the Hanford Site and every attempt is made to minimize pain, stress and discomfort during the collection process. All wildlife samples are collected under permits with Washington Department of Fish and Wildlife and U.S. Fish and Wildlife reveiw. Sample collection staff were trained by the IACUC Attending Veterinarian on the proper procedure for cervical dislocation of mice. Consideration was given to adopting additional steps to apply pre-sampling anesthesia prior to either 1) the collection of field data from trapped animals, or 2) sacrificing the animals for contaminant analysis. In both cases, this additional step would create more stress to the animals than the methods presently used.

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: None. CFR:

Approval Status:
Approved/Disapproved By:
Date:

Disapproved Reason:

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 92-R-0001 CUSTOMER NO. 1046

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

OREGON HEALTH & SCIENCES UNIV.
3181 SW SAM JACKSON PARK RD. #L335
PORTLAND, OR ~~97201~~ 97239
(503) 494-4460

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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			32		32
5. Cats	11		24		24
6. Guinea Pigs			563		563
7. Hamsters			193		193
8. Rabbits			315		315
9. Non-Human Primates	1867	708	988		1696
10. Sheep			269		269
11. Pigs			358		358
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/18/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

NOV 19 2003

Annual Report of Research Facility
Reference: APHIS Form 7023

Oregon Health Sciences University
Main Campus
3180 SW Sam Jackson Park Road
Portland, OR 97239

Certificate Number: 92-R-0001

The OHSU main-campus IACUC has approved the following exceptions (10/1/2002-9/30/2003):

1. One protocol was approved allowing the housing of rabbits for up to 48 hours in primary enclosures that do not allow them to turn around during a period of data collection. The enclosures do allow the rabbits to make most other postural adjustments with adequate freedom of movement. The rabbits are removed every 8 hours and allowed to eat and drink as much as they want during a thirty-minute period. These thirty minute feeding and drinking breaks have been shown to be adequate to maintain body weight. The IACUC accepted scientific justification that this level of restraint is necessary for proper collection of data on these projects. 11 rabbits were affected by this exception.

2. Five protocols were approved allowing investigators to withhold food from sheep for 24 hours prior to surgery. The IACUC accepted scientific justification that ruminants have fewer intra operative complications when fasted for 24 hours. 70 sheep were affected by this exception.

3. Two protocols were approved allowing the housing of sheep for up to three weeks in stanchions that do not allow them to turn around. The sheep are allowed free access to food and water and are able to stand or lie down. The IACUC accepted scientific justification that this restraint is required to allow withdrawal and infusion of fluids through implanted catheters, continuous monitoring of coronary blood flow, and to prevent the sheep from nibbling at the catheters. 27 sheep were affected by this exception.

4. One protocol was approved allowing microswine to be housed for 48 hours in metabolic cages that do not provide the square footage of floor area recommended by the Guide. The metabolic cages are 3 ft by 4 ft and allow the pigs to lie down. The pigs are provided food and water and the cages are cleaned daily. The IACUC accepted justification that the pigs need to be housed in the metabolic cages to allow for collection of urine to determine urinary sodium excretion, metabolic sodium and water balance in a microswine model of hypertension following intrauterine growth retardation. No pigs were affects by this exception.

5. Two protocols were approved allowing multiple major survival surgery in rabbits. The rabbits undergo a laporatomy to implant catheters in the abdominal aorta and vena cava. The rabbits are then allowed to recover for two weeks before a thoracotomy is performed to place an ascending aortic flow probe to measure cardiac output. The IACUC accepted justification that the multiple surgeries were necessary to improve survival rates for the complicated surgeries. 6 rabbits were affected by this exception.

6. One protocol was approved allowing nonhuman primates to be housed in individual cages, which do not permit contact with neighboring caged animals. This study involved developing an animal model for Simian Varicella virus (SVV) infection. The IACUC accepted scientific justification that individually housing animals was necessary in order to establish the efficiency of infection and follow the course of disease. Furthermore, housing these animals individually would prevent the transmission of SVV unless the design called for joint housing to attempt natural exposure. 3 animals were affected by this

exception. Pair housing was attempted for 2 of the animals. These animals were found to be incompatible. Grooming contact bars were used instead. The animals had visual, auditory and physical contact with one another. One animal could not be paired. This animal was housed in the same room as the other 2 animals. A mirror was provided so that he would have visual contact with the other monkeys. He was also able to smell and hear them. Positive interaction with caretakers on a daily basis was provided for all three monkeys used in this study.

Oregon Health and Science University
Oregon Regional Primate Research Center
APHIS Form 7023

Summary of exceptions to the AWA standards and regulations approved by the IACUC October 1, 2002 through September 30, 2003.

1. The IACUC granted exceptions for 2 projects to the AWA standard that nonhuman primates be housed so that they are able to see conspecifics for female rhesus macaques assigned to a specific project. Introduction of new animals to a room can cause stress and alter experimental results. To allow for a smoother introduction period, if a new animal displays consistent signs of stress it is positioned in a way that disallows visual contact with conspecifics, but allows for vocalization. This exception involved four animals for 2 days duration each. The involved animals were significantly calmer with the alteration provided by this exception. The animals were monitored for abnormal behavior and were provided positive interaction frequently each day by animal care and project staff. Project staff worked closely with the Center's Psychological Well Being-Center's staff to insure the well being of these animals. Continual environmental enrichment was provided.

2. The IACUC granted an exception to the AWA standard that nonhuman primates be housed so that they are able to see conspecifics for male rhesus macaques assigned to the time-mated breeding colony. This was considered appropriate for veterinary health and psychological well-being considerations. Twelve adult rhesus macaque males are used to serve approximately 135 adult rhesus macaque females assigned to the time-mated breeding colony. Males are housed with the females approximately 12 days each month. These males are housed in cages that face a wall that has no cages on it. When the adult males are housed across from other males and females, it creates an increased amount of stress for all monkeys in the room due to the males threatening others vocally and by shaking their cages. The Center's Psychological Well-Being staff monitored for signs of abnormal behavior and provided ongoing environmental enrichment. There is frequent positive interaction provided by the animal care staff daily. This exception produces a calmer environment in the 2 rooms where these males reside.

3. The IACUC granted an exception to the AWA standard that nonhuman primates be housed so that they are able to see conspecfics for paired female rhesus macaques in the time-mated breeding program. This exception involved 30 female rhesus macaques housed in locations which do not allow immediate direct visualization of conspecifics for up to 3 continuous days for an average of 3-4 times per year while their cage mate is removed for breeding. These are usually relatively timid animals that become stressed when visually exposed to strange animals. They often have their own infants to care for, receive continued environmental enrichment, are monitored for signs of abnormal behavior by the Center's Psychological Well-Being staff, and are provided with positive interaction with animal care staff daily.

4. The IACUC granted an exception to allow some female rhesus macaques to be briefly housed in a location which did not allow immediate direct visualization of conspecifics. Due to building design features, management, or facility maintenance requirements some monkeys may not be able to see conspecifics for limited periods of time. For example, females which receive top priority for being paired are frequently the more timid

females. A compatible pairing with another timid female produces a dramatic increase in confidence in each partner, however, these paired animals do well living facing the walls, rather than facing a number of more aggressive animals. Monkeys living with visual access to each other typically establish dominance hierarchies similar to those found in a troop. If a monkey, who lost its compatible cage mate were to be immediately moved into a location where it could see other unfamiliar animals, it would suffer two negative psychological impacts simultaneously: 1) having lost its compatible cage mate, a recognized stress factor, and 2) being suddenly faced with strange monkeys, some of whom may present hostile and aggressive signals to the newcomer. Adequate time is necessary to identify a new potential cage partner and appropriately introduce and socialize the new pair to each other.

5. The IACUC granted an exception to the AWA standard that nonhuman primates be housed in specific cage sizes. This exception request involved 23 juvenile rhesus macaques housed in a nursery group cage where the surface dimension is under size but is taller than the standard height. Up to 6 animals are housed together at a time and are representative of the larger end size of group 1 weight category and smaller end size of group 2 weight category. The cage is 14.25 sq. ft. at the base, 67 inches in height and has an interior volume of 79.5 cubic ft. The standard size required for 6 animals of group 2 weight category is 18 sq. ft. and 30 inches tall which yields an interior volume of 45 cubic ft. The cage base reduction is deemed mitigated by the positive environmental enrichment provided and the expanded vertical movement capability. The grouping of young animals provides for better socialization. Furnishing the upper portions of the cage with dendritic branches, suspended perches and hanging toys improves opportunity for exercise. The nursery is staffed more intensively than other alternate areas for which the young animals of concern could be caged allowing for a closer monitoring of their condition.

6. The IACUC granted five project exceptions to the AWA standard that nonhuman primates be housed in specific cage sizes. These involved the reduction of cage space from 4.3 sq. ft. to 4.0 sq.ft. for group 3 weight category adult female rhesus macaques and from 8.0 sq. ft. to 6.0 sq. ft. for group 5 weight category adult male rhesus macaques. The 22 monkeys involved, were instrumented by tethered vascular catheters and/or leads. The animals are fitted and adapted to vests, allowed full range of motion and able to stand up, lie down and move about the cage. The reduction in cage size is deemed necessary to protect the chronic capability of sampling from the animal and to preserve and protect the integrity of the instrumentation which when combined ultimately avails improved data for scientific research. The animals are monitored by animal care providers, project staff and by the Center's Psychological Well-Being staff. The alternative to continuous sampling by tethered instrumentation would entail frequent anesthesia that could have negative impact on the animal's condition as well as the quality of the data itself.

7. The IACUC granted a project an exception to the AWA standard for cage size to allow for pairing of adult female rhesus macaques up to 11.7 kg in weight (group 4, > 10 kg) in 4.3 sq. ft. tandem cages. This is a 4 year project and pairing of animals will allow for enhancement of their psychological well-being. Pair caging larger than tandem 4.3 sq. ft. is not possible in these project locations. There were 2 monkeys tangential to this exception. Most of these were a fraction of a kg over 10.0 kg. The involved animals were put on a gradual weight reduction program, given food treat motivators such as peanuts and raisins in place of high sugar treats, separated by cage slides at feeding time when appropriate and were monitored to target management needs to maintain their weights below 10.0 kg. At the end of the reporting period 1 animals remained over 10 kg.

8. The IACUC granted exception to the AWA standard for cage size to allow caging of up to 6 adult male rhesus macaques of group 4 weight category (between 10-15kg) into group 3 weight category, 4.3 sq. ft. cages for up to 14 days. This allowed placement of animals in side by side cages with mesh screens to avail a familiarization period prior to the placement of these males into a group housing environment. This action helped to reduce aggressive trauma that can happen when males are placed in group housing with unfettered contact of each other. The only cages available for this arrangement are group 3 weight category, 4.3 sq. ft. cages. Three animals were tangential to this exception during the reporting period. These animals were monitored by the Center's Psychological Well-Being and Animal Husbandry staff upon their placement in the aforementioned cages for symptoms of stress. No animals had to be returned to their home cage.

9. The IACUC granted 2 projects an exception to the AWA standards for cage size to allow for group 5 category adult male rhesus macaques (up to 25 Kg) to be housed temporarily in Group 4, 6.0 sq. ft. by 32 inch high caging. This exception was granted to allow consolidation of project animals into a central area that allowed for diet and protocol activity to be uniform. All animals involved were within 2 Kg or less of the Group 4 category (up to 15 Kg). One project involved 2 animals for a two week period and the other project involved 4 animals for variable durations up to 4 months. At the end ofthe reporting period, alterations were completed so that all animals were housed in appropriate size caging. All monkeys were monitored multiple times daily by the Centers Clinical, Psychological Well-Being and the individual project laboratory staff for evidence of abnormal health conditions.

10. The IACUC granted a project an exception to the AWA standards regarding feeding so that 25 adult rhesus macaques could be fed a 30% caloric reduced diet. This regime and most of the monkeys assigned to it, are part of an ongoing caloric restricted study that originated over a decade ago at the National Institute ofAging facility in Poolsville, Maryland. Newly assigned monkeys to the 30% caloric reduced diet will have their diet calorie content gradually reduced over a 2 month period. This diet has the same composition of protein, carbohydrates and fat as standard monkey chow but in order to insure adequate administration of vitamins and minerals with a reduced volume fed, the vitamins and minerals have been enriched. Treats and food motivators consisting of but not limited to fruit, vegetables, unsalted crackers and frozen treats will be given daily. All monkeys will be monitored 3 times daily for behavioral deviations, excrement production and for the quantity of food consumed. If monkeys spontaneously decrease their food intake or body weight by more than 30% of their initial baseline levels, veterinary services will be summoned. In addition to possible veterinary prescribed procedures, diet alterations may include the feeding of a highly palatable caloric rich substance or supplementation by enteral administration.

11. The IACUC granted the Time Mated Breeding program an exception to the AWA standards for allowed number of research directed major survival surgeries for adult female rhesus macaques. Availability of rhesus macaques that cycle well and provide consistent pregnancies is extremely limited at NIH supported research facilities. Allowance for the increase to a total of 4 major survival surgeries (hysterotomies) on up to 2 different projects will expand the capability of reproductive studies and refine the efficient use of this limited nonhuman primate resource. Within the reporting period, 31 animals were tangential to the exception. The current exception approval was granted by Chester A. Gibson, Acting Deputy Administer, Animal Care, USDA for a period from March 1, 2002 to February 28, 2005 for up to 100 animals. A total of47 animals are

tangential within this current exception time frame. The exception carries the following requirements:
1) All animals under this exemption must be permanently identified.
2) Complete health records must be maintained on each animal. These must include the name of any medication administered, as well as the dose, route and frequency/time of administration and a description of any complications that may arise. Health records must accompany the animals used in this study to any future studies.
3) The time between hysterotomies for catheter/electrode placement and fetus/tissue collection must be maximized to the extent permitted by the experimental design. The time between sets of hysterotomies will be no less then 6 months.
4) Appropriate post-operative analgesia is described; it is suggested that consideration be given to intra-operative or other pre-emptive analgesic administration.
5) An annual IACUC evaluation of this exemption is required; including an assessment of the animals as well as the effectiveness and soundness of the methods and procedures used on them. Particular attention should be paid to the procedures used to minimize pain and distress. This information must be included in the IACUC reports required under Section 2.35(a)(1).
6) The subject animals must not undergo any other major survival surgery unless justified in accordance with 9 CFR, Part 2, Section 2.31(d)(x)(C).

12. The IACUC granted an exception to the AWA standards for allowed number of research directed major survival surgeries for nonhuman primates for a specific project. This exception allows up to 20 adult female rhesus macaques per year for 3 years, that have had major survival surgery on a previous project to receive one additional major survival surgery on the exception granted project. The project requires that normal cycling females be ovariectomized. This creates a competition of use with reproductive studies that are limited presently due to the depressed existing quantity and the difficult acquisition of normal cycling rhesus macaques. Allowing the initial use of normal cycling monkeys to be assigned to reproductive studies especially protocols that end with an ovariectomy prior to use on the exception granted project, would enhance the efficient use of this limited nonhuman primate resource. One animal was tangential to this exception during this report period. This exception was approved by W. Ron DeHaven, Deputy Administrator, Animal Care, USDA, for the period August 1, 2001 to July 31, 2004 with the following requirements:
1) All animals must be permanently identified.
2) Complete health records must be maintained on each animal. These must include the name of any medication administered, as well as the dose, route and time of administration.
3) The second major survival operative procedure will be performed no sooner than four months after the ovariectomy. Appropriate perioperative analgesia must be provided to the animals as directed by your attending veterinarian, and it is suggested that you carefully consider administration of analgesics pre-emptively.
4)An annual IACUC evaluation of the exemption is required; including an assessment of the animals as well as the effectiveness and soundness of the methods and procedures used on them. Particular attention should be paid to the procedures used to minimize pain and distress. This information must be included in the IACUC reports required under Section 2.35(a)(1).

13. The IACUC granted an exception to the AWA standards for allowed number of research directed major survival surgeries for nonhuman primates for a specific project. This exception allows for up to 3 additional laparotomies to be performed on up to 11 adult female rhesus macaques. The aim of a portion of the protocol is to perform laparoscopic surgery to harvest targeted ovarian tissue. Some of the assigned animals have had prior

major surgery and adhesions may negate the abilities to harvest tissue by laparoscopic surgical methods. Procurement of tissue would then necessitate a laparotomy. Three separate surgeries for tissue sampling are planned for each animal. This is a long term study that contains some animals that are age matched controls and others that are caloric restricted and all have well-defined reproductive histories. As a resource these animals are extremely rare and valuable and like substitution is not possible. For this reporting period, no animals were tangential to this exception. This exception was approved by Chester A. Gibson, Acting Deputy Administrator, Animal Care, USDA, for the period April 1, 2002, to March 31, 2005 with the following exceptions:
1) All animals must be permanently identified.
2) Complete health records must be maintained on each animal. These must include the name of any medication administered, as well as the dose, route and frequency/time of administration and a description of any complications that may arise. Health records must accompany the animals used in this study to any future studies.
3)The time between laparotomies will be no less then 2 months.
4) Appropriate post-operative analgesia is described; it is suggested that consideration be given to intra-operative or other pre-emptive analgesic administration.
5) An annual IACUC evaluation of this exemption is required; including an assessment of the animals as well as the effectiveness and soundness of the methods and procedures used on them. Particular attention should be paid to the procedures used to minimize pain and distress. This information must be included in the IACUC reports required under Section 2.35(a)(1).
6) The subject animals must not undergo any other major survival surgery unless justified in accordance with 9 CFR, Part 2, Section 2.31(d)(x)(C).

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 92-R-0001
Customer Number: 1046
Facility: OREGON HEALTH & SCIENCE UNIVERSITY
3181 SW SAM JACKSON PARK RD. , #L335
PORTLAND, OR 97239
(503) 494-4460

A. Comparative Medicine – MRB/Vollum Institute/CROET
3181 SW Sam Jackson Park Rd.
Portland, OR 97239

B. Casey Eye Institute
3181 SW Sam Jackson Park Rd.
Portland, OR 97239

C. Hatfield Research Center
3181 SW Sam Jackson Park Rd.
Portland, OR 97239

D. Oregon National Primate Research Center
505 NW 185th Ave.
Beaverton, OR 97006

E. Neurological Sciences Institute/Vaccine & Gene Therapy Inst.
505 NW 185th Ave.
Beaverton, OR 97006

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 2150.

See reverse side for additional information

Interagency Report Control No 0180-0OA-AN

Laris

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0026 CUSTOMER NO. 1182

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

SRI INTERNATIONAL
333 RAVENSWOOD AVENUE
MENLO PARK, CA 94025
(650) 859-4771

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)*

See Attached Listing

Buildings T, K and L

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	2	22	10	55	89
5 Cats					0
6 Guinea Pigs				5	5
7 Hamsters					0
8 Rabbits	1	526	12	7	546
9 Non-Human Primates					0
10 Sheep					0
11 Pigs					0
12 Other Farm Animals					0
13 Other Animals					0

RECEIVED NOV 23

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 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)

OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/21/01

APHIS FORM 7023 (AUG 91)

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

PART 1 - HEADQUARTERS

Column E Explanation

1.) Registration Number: **93-R-0026**

2.) Number of animals used in these studies **(55).**

3.) Species (common name) of animals used in these studies **Dog**.

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

The object of these studies (6 total) was to establish any potential drug toxicity of novel compounds in the initial evaluation stages of becoming therapeutics for various human disorders/diseases. The effects of these compounds in whole, live animals were being evaluated in order to determine their relative safety/toxicity.

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)

Category E was selected for these studies during the initial review of animal research protocols because they involve administration of novel compounds with uncharacterized toxicity potentials. Anesthetics or analgesics are not administered during these studies due to possible effects on the metabolism, uptake, and elimination of the novel compounds that could alter research data and ultimately the interpretation of that data.

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: **Federal Drug Administration (FDA) 21 CFR 312.23, a,5,ii,iii**

An Investigational New Drug (IND) submission requires: "A summary of the pharmacological and toxicological effects of the drugs in animals."

Column E Explanation

1.) Registration Number: 93-R-0026

2.) Number of animals used in these studies (5).

3.) Species (common name) of animals used in these studies **Guinea Pig.**

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

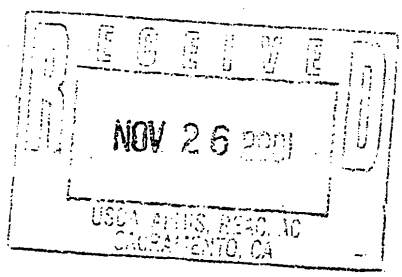
The object of these studies (2 total) was to develop treatments for cocaine and opiate-abuse disorders. The study required obtaining chemical-free tissues from animals by euthanizing them by decapitation.

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)

Category E was selected for these studies because decapitation without the prior use of anesthetics is the method of choice for these studies. Anesthetics or analgesics interfere with determining binding and biological activity of drugs of abuse and could not be used because of possible interference with research results. Studies have been conducted comparing this form of euthanasia with other methods and it was found that tissue obtained in this manner was necessary for the subsequent *in vitro* assays.

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: N/A



Column E Explanation

1.) Registration Number: **93-R-0026**

2.) Number of animals used in this study (7).

3.) Species (common name) of animals used in this study **Rabbit.**

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

The object of this study (1 total) was to determine the pharmacokinetics and absorption, distribution, metabolism and excretion of novel compounds in the initial evaluation stages of becoming therapeutics for various human disorders/diseases. The effects of these compounds in whole, live animals were being evaluated in order to determine their relative safety/toxicity.

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)

Category E was selected for these studies during the initial review of animal research protocols because they involve administration of novel compounds with uncharacterized toxicity potentials. Anesthetics or analgesics are not administered during these studies due to possible effects on the metabolism, uptake, and elimination of the compounds that could alter research data and ultimately the interpretation of that data.

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: **Federal Drug Administration (FDA) 21 CFR 312.23, a,5,ii,iii**

An Investigational New Drug (IND) submission requires: "A summary of the pharmacological and toxicological effects of the drugs in animals."

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 2150.

See reverse side for additional information.

Interagency Report Control N
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0029 | CUSTOMER NO. 1180

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

3431 HILLVIEW AVENUE
PALO ALTO, CA 94304
(650) 855-5384

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	160	131	205	0	496 336
5. Cats	8	0	37	0	45 37
6. Guinea Pigs	0	72	0	0	72
7. Hamsters	0	0	0	0	0
8. Rabbits	20	180	196	0	396 376
9. Non-Human Primates	165	149	60	8	382 217
10. Sheep	0	0	0	0	0
11. Pigs	1	0	10	0	11 10
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		21 NOV 03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

NOV 24 2003

Roche

01 Oct 02 – 30 Sept 03
APHIS Form 7023

Column E Explanation

1. Registration number: **93-R-0029**
2. Number **6** of animals used on this study.
3. Species (common name) cynomolgus
4. Explain the procedure producing pain or distress:

Monkeys are trained to depress a switch for food. When a green light is on, switch presses result in the delivery of food and a mild foot-shock. (Monkeys are not required to depress the switch and can avoid the shock)

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)

Shock levels are individually adjusted for each monkey and are minimized to produce an irritation. Under these conditions, monkeys respond to anti-anxiety drugs, and this method is a well-established assay for anti-anxiety drugs. The administration of analgesics or other compounds will attenuate the models response to a noxious stimulus.

Roche

01 Oct 02 – 30 Sept 03
APHIS Form 7023

Column E Explanation

1. Registration number: **93-R-0029**
2. Number **2** of animals used on this study.
3. Species (common name) **cynomolgus**
4. Explain the procedure producing pain or distress:

Two monkeys may have experienced pain or distress when used on a safety study to evaluate the toxicity of a new drug.

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)

Both animals were found dead after being observed as clinically normal 40 to 90 minutes prior to death. Therefore, since there was no indication of pain or distress upon the most recent observation, no pain relieving drugs or veterinary attention was implemented.

Roche

01 Oct 02 – 30 Sept 03

Registration number: 93-R-0029

Summary of IACUC Approved Deviations from USDA Standards

Thirteen dogs were exempted from regular exercise periods for a span of 10 – 42 days following the administration of a radiolabeled compound for mass balance metabolism studies. They were confined to individual metabolism cages to allow for the collection and isolation of radioactive urine and feces. The cage size conformed to USDA standards and they were in visual or olfactory and auditory contact with other dogs at all times. During confinement they received extra attention and human interaction with the study research associates.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0050 **CUSTOMER NO.** 1173

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF THE PACIFIC
3601 PACIFIC AVE
STOCKTON, CA 95211

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)*

UNIVERSITY OF THE PACIFIC
STOCKTON, CA 95211

UNIVERSITY OF THE PACIFIC
SAN FRANCISCO, CA 94115

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		8	23		31
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats		110		30	140

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/24/2003

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

1. Registration Number: 93-R-0050 / 1173

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

Rats (30)

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

Animals will undergo constriction of the IoN under sodium pentobarbital anesthesia (see above). This involves surgical exposure of the nerve within the orbit and the placement of a single ligature (5-0 chromic gut). In sham-injury rats the nerve will be exposed only. The surgical incisions will be sutured with 6-0 silk sutures. In some animals the effects of a prior unilateral sympathectomy on the development of neuropathic pain will be studied. Under anesthesia, the right superior cervical ganglion will be exposed and surgically removed. The animals will be allowed to heal 3-4 weeks before chronic nerve constriction. The surgical incision will be sutured with 4-0 Ethicon sutures. Prior to surgery the animals will be treated with an antibiotic (Crystoben, 0.1 ml) and an analgesic (acetaminophen in drinking water) is administered over the following two days.

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)

No medications will be given for post-operative pain, as they may alter the neuroinflammatory interactions that occur after nerve injury. In addition, the biochemical and physiological changes in both the peripheral nerve and CNS can be affected by the administration of analgesics and local anesthetics. This would severely compromise the main objective of the study, which is to correlate the development of a painful neuropathy with anatomical and physiological parameters. The development of infection at the site of surgery would result in the loss of the animal from the study. Therefore, prophylactic administration of an antibiotic is intended control this potential variable.

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: CFR:

Approval Status:
Approved/Disapproved By:
Date:

Disapproved Reason:

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0200 CUSTOMER NO. 1139

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

BIOSURG
27956 STATE HWY 128
WINTERS, CA 95694
(916) 795-2356

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	1		5		5
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			2		2
9. Non-Human Primates	2				
10. Sheep	13		62		62
11. Pigs	4		51		51
12. Other Farm Animals calves	7		17		17
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.

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.

OCT 26 2001

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
		10-3-01

APHIS 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	93-R-0200
Customer Number:	1139
Facility:	BIOSURG 27956 STATE HWY 128 WINTERS, CA 95694 (916) 795-2356

BIOSURG
27956 STATE HWY 128
WINTERS, CA 95694

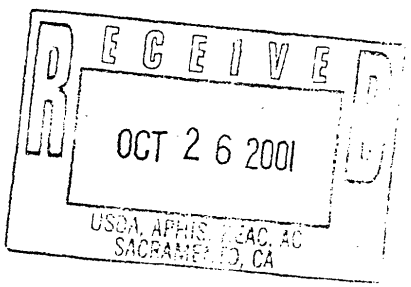
October 4, 2001

USDA Annual Report of Research Facility 93-R-0200

Explanation of exception to the standard as stated in section 3.128

Sheep and calf's weighing between 25-50 kg. Were given enclosures of 14 square feet, secured to restrict movement to 3 feet forward and 3 feet backward, and could have been the only animal in the room. The duration of the study lasted up to 90 days in some cases. The animals were able to rise normally and lie down normally, they could not turn around. The nature of the power source to the implanted device would not allow for interruption of the current or the animal would die within 2 minutes. Animal care personnel were present in the room 24 hours per day to provide care and social enrichment. During 2 studies 2 animals were present in the room at the same time.

Attached is a sample of the Exemption from Social Interaction or Environmental Requirements for Research Animals. The animals were observed by one or more of the IACUC at 2-week intervals and the form was completed, signed and added to the animal's record. Signs of distress, behavior problems, weight loss, appetite changes and any medical conditions were reviewed by the IACUC at this time and noted on the Exemption from. No adverse conditions ever occurred in these animals.



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 2150.

See reverse side for additional information.

Interagency Report 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0280 **CUSTOMER NO.** 1117

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

ELAN PHARMACEUTICALS, INC.
800 GATEWAY BLVD.
SAN FRANCISCO, CA 94080

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)*

ELAN PHARMACEUTICALS, INC.
SAN FRANCISCO, CA 94080

GENZYME TRANSGENICS CORP
CHARLTON DEPOT, MA 01509

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		11	991	274	1276
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/22/2003

APHIS FORM 7023 **(AUG 91)**

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

PART 1 - HEADQUARTERS

1. Registration Number: 93-R-0280 / 1117

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

Guinea Pigs (274)

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

Introduction EAE is an autoimmune disease involving the central nervous system and is widely used as an animal model for multiple sclerosis (MS), a human demyelinating disease for which there is no known cause and no suitable treatment. MS is the most common disease of the central nervous system affecting young people (20-40 years old). It is estimated that there are 250,000 people in the United States with MS. MS is characterized by exacerbation and remissions of neurological dysfunction such as loss of muscle control, limb numbness, paralysis, blurred vision and blindness. An autoimmune reaction against spinal cord proteins is the hallmark of both human MS and guinea pig EAE. Procedure Immunization Anesthetize young adult or juvenile guinea pigs with 2.5% Isoflurane carried in 100% oxygen through a vaporizer. Shave the injection site on both flank areas and wipe with betadine or alcohol swab. Immunize each guinea pig by subcutaneous injection in shaved area with the immunogen emulsion. Each animal receives 75-150mg GPBSC / 1-3mg MT / 0.3 - 0.6ml. Guinea pigs with a clinical score of no less than a 2 on Day 40 onwards will be treated with a positive control or test drug until termination. These treatments will be given by any of the following routes: subcutaneous, intravenous, intraperitoneal, or oral. Blood may be taken from some guinea pigs (via cardiacpuncture under anesthesia) at the termination of the experiment so that blood levels of drug may be estimated. Animals that have blood drawn via cardiac puncture will not be allowed to recover from the anesthesia. Guinea pigs will be euthanatized at different time points during the experiment for the histological examination of their brain and spinal cord. All guinea pigs that have not attained a clinical score of 2 by day 40 will be euthanized by CO2 asphyxiation followed by thoractomy. Post immunization care After immunization, the guinea pigs are checked daily for the first week for signs of infection at the site of immunization. The body weight and clinical score will be checked 2-3 times per week until animal shows clinical signs of disease and at least once per day after onset of the disease. The immunized animals are expected to develop hind limb paralysis approximately 10-17 days post immunization. When the animals develop hind limb paralysis, they will be checked daily or more often until the paralysis has completely resolved. In some cases, food will be placed on the bottom of the cage for ad libitum consumption by guinea pigs that have motor impairment. Saline (3-10ml per guinea pig per day) or heating pad (on low) may be supplied if necessary. If any animal is clearly moribund (quadriplegia, blood urine, foaming at the mouth), the guinea pig will be euthanized.

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)

The guinea pigs may experience some pain after the immunization. During the paralysis, the guinea pigs do not appear to experience acute or surgical type pain. They are active and do not show behavior typical of guinea pigs in pain, but they likely experience symptomatic distress resulting from the disease. The disease can cause dehydration, atonic bladder, fecal impaction and weight loss. Continuous administration of pain ameliorating drugs will interfere with the results of experiment and is not likely to relieve the pain or distress related to these symptoms. These symptoms are each addressed individually in the ?post immunization care? section of this protocol and in Table1. We hope that our treatments will prevent the paralysis and the distress, so that only 30% of the guinea pigs (the negative control group) in a study may experience the temporary paralysis.

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: CFR:

Approval Status:
Approved/Disapproved By:
Date:

Disapproved Reason:

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 2150.

See reverse side for additional information.

Interagency Report 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0287 CUSTOMER NO. 3388

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

INTERNATIONAL IMMUNOLOGY CORPORATION
25549 ADAMS AVENUE
MURRIETA, CA 92562

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)*

INTERNATIONAL IMMUNOLOGY CORPORATION
MURRIETA, CA 92562

INTERNATIONAL IMMUNOLOGY CORPORATION
MURRIETA, CA 92562

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					
Goats	73	550		62	612
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/03/2003

1. Registration Number: 93-R-0287 / 3388

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

Goats (62)

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

The use of Freund Complete Adjuvant (CFA) for the production of antibodies may cause results ranging from momentary or slight pain, to distress such as decrease appetite/activity level, open sores/necrotic skin lesions, abscesses. IIC employs the use of minimal amounts of CFA (among other commercially available adjuvants)in the production of polyclonal antibodies, and is committed to insure that the animals receive any care necessary to relieve symptoms noted above.The least amount of CFA possible is used per injection site and per animal to obtain acceptable immune response, and the animals are monitored twice daily to insure their welfare. Any goat appearing to show distress is reported to the Animal Operations Manager and appropiate steps are taken to relieve such condition.Analgesic drugs are employed if there are observable signs of pain or distress.

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)

IIC's management team continuoely strives to ensure proper care is taken of our animals. It is imperative that our goats maintain a long, healthy life, as the antibodies they produce represent the primary source of revenue for our company. Our goal is to produce a high quality product for the medical diagnostic industry while employing the least stressful means with respect to our animals. This is accomplished by careful observation of the animals as well as a continuos refinement of our procedures and techniques. Wherever possible we employ alternative adjuvants such as RIBI (Corixa)and Incomplete Freund Adjuvant (IFA). We also remain vigilant with respect of new industry developments by performing database searches on alternatives to the use of CFA. Complete Freund Adjuvant still plays an important role in our ability to produce quality material. We continue to strive to maintain a delicate balance between our animals welfare and the quality of our product. The following are examples of the information sources we employ: Guidelines on: Antibody Production, Canada Council on Animal Care, 2002 ILAR Journal Articles.Vol. 37, Number 3, 1995: Review of Polyclonal Antibody Production Procedures in Mammals and Poultry. Review of Selected Adjuvants Used in Antibody Production. Institutional Policies and Guidelines on Adjuvants and Antibody Production. Harlow & Lane. Antibodies, A Laboratory Manual. Cold Spring Harbor Laboratory, 1988. A Comparison of Commercially Available Adjuvants for Use in Research, Journal of Immunological Methods, 153, 1992. Howard & Bethell. Antibodies Production and Characterization, CRC Press, 2001. Ian Tizard. Veterinary Immunology. W.B. Saunders Company, 1996. M. Podolsky & V. Lukas. The Care and Feeding of an IACUC, CRC Press, 1999. AWIC Resource Series No 7. Information Resources for Institutional Animal Care and Use Committees, Sept 1999, Rev. 2000. ECVAM Workshop 35. The Production of Polyclonal Antibodies in Laboratory Animals. 1998.

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: APHIS, Animal Care Policy Manual, Policy #11 and #12.; 9 CFR Part 2, Section 2.28.; 9 CFR Part 3, Section 3.134. CFR:

Approval Status:
Approved/Disapproved By:
Date:

Disapproved Reason:

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0348 | CUSTOMER NO. 1249 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

BERLEX BIOSCIENCES
2600 Hilltop Drive
Richmond, CA 94804
(510) 262-5000

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)*

See Attached Listing

2600 Hilltop Dr., Richmond, CA

COPY

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	0	21	5	1	27
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	84	12	0	96
8. Rabbits	0	186	0	6404 -0 3	~~186~~ 189
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	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, 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 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)

SI	L OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
			12-3-03

APHIS FORM 7023
(AUG 91)

Oct 88), which is obsolete

PART 1 - HEADQUARTERS

JUN 14 2004

DEC 4 2003

Exemption:

For the duration of one week after medical device implantation, animals assigned to the protocol were exempt from group exercise. This exemption was reviewed and approved by the ACUC. Study animals were housed in the study room in typical one- over- one cages approved for the laboratory animals. This exemption was instituted as a safety measure in order to closely monitor animals during their post-surgical recovery period. During this period of time all animals received additional positive human contacts several times per each day.

Animals Listed in Column E:

In year 2003, a total of three rabbits were euthanized due to adverse effects of the experimental compounds. Additionally, one dog experienced some degree of complications associated with the implantation of medical devices and subsequently this animal was euthanized.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0348 CUSTOMER NO. 1249

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

BERLEX BIOSCIENCES
15049 SAN PABLO AVE
RICHMOND, CA 94086
(510) 262-5000

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)*

See Attached Listing	
15049 San Pablo Ave., Richmond, CA	94804

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	12	12	86	0	98
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	30	246	0	276
7. Hamsters	0	54	0	0	54
8. Rabbits	9	0	103	0	103
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Gerbil	10	0	105	0	105

RECEIVED NOV 21 2001

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/20/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 3 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

Exception Summary

Our Animal care and Use Committee reviewed and approved two exemptions for dog exercise. Dogs recovering from surgery or included in a chronic drug dosing study were exempted from daily routine exercise for up to three weeks.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0353 CUSTOMER NO. 1253

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

PARKINSON'S INSTITUTE, THE
1170 MORSE AVENUE
SUNNYVALE, CA 94089
(408) 734-2800

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)*

See Attached Listing

Animal Facility rooms: 132, 136, 142, 143

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	0	60	0	10	70
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.

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)

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

DATE SIGNED 11-19-03

[redacted]

APHIS FORM 7023 — (Replaces VS FORM 18-23 (Oct 88), which is obsolete
AUG 91)

Part 2 Sector Office

Updated on 10/8/02

Category E Justification Statement
For 2002 – 2003 USDA Annual Report

_____10___ animals were included in the "E" category because these animals were on studies involving induction of Parkinson's disease. This process involves injection of MPTP (1-methyl-4-phenyl-1,2,3,6-Tetrahydropyridine), a neurotoxin that selectively destroys nigrostriatal dopaminergic neurons. Presumably, there is some psychological distress associated with the temporary impairment of motor function experienced by these animals. In addition, there may be some temporary systemic side effects related to the chemical induction agent. In humans, Parkinson's disease causes increasing motor impairment and a portion of our research into the nature and possible treatment of this disorder involves induction of the disorder in living animals. In particular, non-human primates represent the only animal model in which the behavioral, neurochemical and neuropathological features of Parkinsonism are fully expressed and thus they are the best models for studies on Parkinson's disease. Based on our experience in humans, this disorder is not known to cause physical pain; however, animals may experience some distress during the time they have diminished motor function. We have strong reason to believe that this statement is correct, since we have cared for a number of humans with a form of Parkinsonism identical to that experienced by these animals, and none had pain. The impairment in our experimental studies cannot be alleviated since it is necessary to the objectives of our studies. Use of sedatives or tranquilizers is also not justified because the effects of these agents would interfere with the results of our investigations. Nor is it justified on purely medical grounds, since pain, psychosis, or agitation is not a part of this syndrome based on our experience in humans.

Registration Number: 93-R-0353
Saimiri Sciureus (Squirrel Monkey)

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

Laris

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0353 CUSTOMER NO. 1253

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

PARKINSON'S INSTITUTE, THE
1170 MORSE AVENUE
SUNNYVALE, CA 94089
(408) 734-2800

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)*

See Attached Listing
Animal Facility Rms.131, 132, 136, 143.

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	0	34	0	6	40
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/18/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

RECEIVED
OCT 23 2001
USDA, APHIS, REAC, AC
SACRAMENTO, CA

APHIS Form 7023 Site List

The following sites have been reported by the facility.

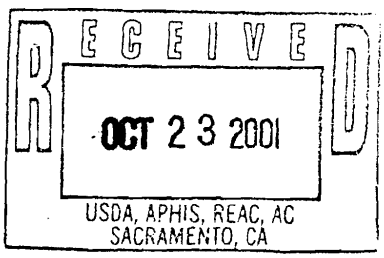
Registration Number: 93-R-0353
Customer Number: 1253
Facility: PARKINSON'S INSTITUTE, THE
1170 MORSE AVENUE
SUNNYVALE, CA 94089
(408) 734-2800

THE PARKINSON'S INSTITUTE
1170 MORSE AVENUE
SUNNYVALE, CA 94089

Category E Justification Statement
For 2000 - 2001 USDA Annual Report

Six animals were included in the "E" category because these animals were on studies involving induction of Parkinson's disease. This process involves injection of MPTP (1-methyl-4-phenyl-1,2,3,6-Tetrahydropyridine) , a neurotoxin that selectively destroys nigrostriatal dopaminergic neurons. Presumably, there is some psychological distress associated with the temporary impairment of motor function experienced by these animals. In humans, Parkinson's disease causes increasing motor impairment and a portion of our research into the nature and possible treatment of this disorder involves induction of the disorder in living animals. In particular, non-human primates represent the only animal model in which the behavioral, neurochemical and neuropathological features of Parkinsonism are fully expressed and thus they are the best models for studies on Parkinson's disease. Based on our experience in humans, this disorder is not known to cause physical pain; however, animals may experience some distress during the time they have diminished motor function. We have strong reason to believe that this statement is correct, since we have cared for a number of humans with a form of Parkinsonism identical to that experienced by these animals, and none had pain. The impairment in our experimental studies cannot be alleviated since it is necessary to the objectives of our studies. Use of sedatives or tranquilizers is also not justified because the effects of these agents would interfere with the results of our investigations. Nor is it justified on purely medical grounds, since pain, psychosis, or agitation is not a part of this syndrome based on our experience in humans.

Registration Number: 93-R-0353
Saimiri Sciureus (Squirrel Monkey)



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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0370 CUSTOMER NO. 1300

FORM APPROVED OMB NO. 0579-0036 Laris

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

ENDOCRINE TECHNOLOGIES, INC.
35325 FIRCREST STREET
NEWARK, CA 94560
(510) 745-0844

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	N/A				NIL
5. Cats	N/A				NIL
6. Guinea Pigs	N/A				NIL
7. Hamsters	N/A				NIL
8. Rabbits	25	25	N/A	N/A	25
9. Non-Human Primates					NIL
10. Sheep					NIL
11. Pigs					NIL
12. Other Farm Animals					NIL
					~~NIL~~
13. Other Animals					NIL
Mice	20	20			~~[illegible]~~ 20 RE

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/28/01

RECEIVED
DEC 4 2001
USDA, APHIS, PPAC, AC

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete)

PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	93-R-0370
Customer Number:	1300
Facility:	ENDOCRINE TECHNOLOGIES, INC. 35325 FIRCREST STREET NEWARK, CA 94560 (510) 745-0844

ENDOCRINE TECHNOLOGIES, INC.
35325 FIRCREST STREET
NEWARK, CA 94560

ENDOCRINE TECHNOLOGIES, INC.
1115 MARINE VIEW DRIVE
VISTA, CA 92083

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 93R037O

2. Number 25 of animals used in this study.

3. Species (common name) Rabbits of animals used in the study.

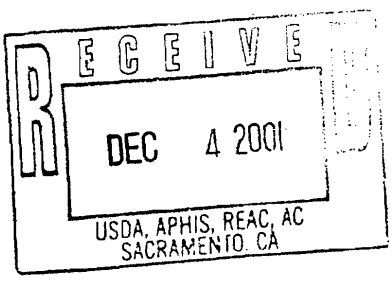
4. Explain the procedure producing pain and/or distress.
Endocrine experiments involve developing antibodies in rabbits. The protocols involve simple injections and no pain / distress is caused to the animals.

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)

N/A

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 _____ CFR _____



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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0375 CUSTOMER NO. 1308

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

THE NEUROSCIENCES INSTITUTE
10640 JOHN JAY HOPKINS DRIVE
SAN DIEGO, CA 92121
(858) 626-2000

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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		2	2	0	4
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11-14-01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

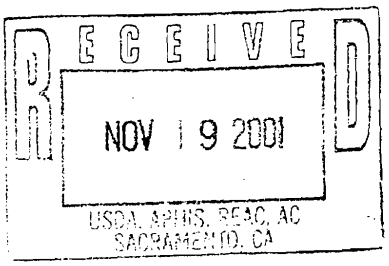
PART 1 - HEADQUARTERS

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	93-R-0375
Customer Number:	1308
Facility:	THE NEUROSCIENCES INSTITUTE 10640 JOHN JAY HOPKINS DRIVE SAN DIEGO, CA 92121 (858) 626-2000

THE NEUROSCIENCES INSTITUTE
10640 JOHN JAY HOPKINS DRIVE
SAN DIEGO, CA 92121



Attachment

United States Department of Agriculture
Animal and Plant Health Inspection Service
Annual Report of Research Facility (Form 7023)
October 1, 2000 through September 30, 2001

The Neurosciences Institute
Registration # 93-R-0375

Summary of Exceptions to the Standards and Regulations Under the Act

1) An investigator was granted IACUC approval to perform multiple survival surgeries on the same non-human primate as part of the same experimental protocol. During this reporting period, two primates were used.

2) An investigator was granted IACUC approval to use carefully monitored water scheduling as a motivational and training tool for non-human primates. Animals receive less than four hours of free access to water for five or six days per week during part of the protocol, when they receive water or other liquids during the day as a reward for performing tasks. They have free access to water at all times on the other days. Guidelines are in place to ensure that the animals receive adequate amounts of water to support their health and well-being. During this reporting period, four primates were used.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0397 CUSTOMER NO. 1753

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

B. BRAUN MEDICAL INC.
2525 MCGAW AVENUE
IRVINE, CA 92614
(714) 660-2954

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)*

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	10	6	0	16
5. Cats	0	0	0	0	0
6. Guinea Pigs	50	830	0	1,760	2,590
7. Hamsters	0	0	0	0	0
8. Rabbits	0	5,825	509	0	6,334
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	9	0	9
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	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, 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 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)

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

DATE SIGNED 11-24-03

APHIS FORM 7023
(AUG 91)

~~This obsolete~~

PART 1 - HEADQUARTERS

DEC 3 2003

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 93-R-0397

2. Number 1,760 of animals used in this study.

3. Species (common name) Guinea Pigs of animals used in the study.

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

   Animals developed lesions associated with Freunds complete adjuvant injected intradermally.

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)

   Freund's adjuvant was used per the FDA guidance document and ISO10993. A thorough literature review was conducted during the past year to investigate an alternative to Freund's. Current consensus is that although there are other adjuvants on the market, none creates an immunogenic response as readily as Freund's.

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 FDA Center for Devices and Radiological Health ~~CFR~~ General Program Memorandum (G95-1)

   See Attached (6 Pages)

DEC 3 2003

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150 additional information

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 1753 93-R-0397

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

B. Braun Medical Inc.
2525 McGaw Avenue
Irvine, CA 92614

Telephone:
(714) 660-2854

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)*

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	0	32	12	0	44
5. Cats	0	0	0	0	0
6. Guinea Pigs	150	946	0	2320	3266
7. Hamsters	0	0	0	0	0
8. Rabbits	198	9259	1003	0	10262
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	8	0	8
11. Pigs	1	0	110	0	110
12. Other Farm Animals					
13. Other Animals					

RECEIVED
DEC 6 2001
USDA, APHIS, REAC, AC
SACRAMENTO, CA

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

PART 1 – HEADQUARTERS

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 93-R-0397

2. Number 2320 of animals used in this study.

3. Species (common name) Guinea Pigs of animals used in the study.

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

   Animals developed lesions associated with Freunds complete adjuvant injected intradermally.

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)

   Freund's adjuvant was used per the FDA guidance document and ISO10993. A thorough literature revuew was conducted during the past year to investigate alternatives to Freund's. Current consensus is that although there are other adjuvants on the market, none create an immunogenic response as readily as Freund's.

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 _____ CFR _____

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0449 CUSTOMER NO. 11593

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

AVANIR PHARMACEUTICALS
11388 SORRENTO VALLEY ROAD, STE 200
SAN DIEGO, CA 92121
(858) 622-5227

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.) 11388 and 11404 Sorrento Valley Rd., San Diego, CA 92121

FACILITY LOCATIONS(sites)

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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					NA
5. Cats					NA
6. Guinea Pigs	44			668	712 668
7. Hamsters					NA
8. Rabbits					NA
9. Non-Human Primates					NA
10. Sheep					NA
11. Pigs					NA
12. Other Farm Animals					NA
13. Other Animals					NA

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/26/03

APHIS FORM 7023 (AUG 91)

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

PART 1 - HEADQUARTERS

NOV 28 2003

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	93-R-0449
Customer Number:	11593
Facility:	AVANIR PHARMACEUTICALS 11388 SORRENTO VALLEY ROAD, STE 200 SAN DIEGO, CA 92121 (858) 622-5227

11388 SORRENTO VALLEY ROAD, STE 200
SAN DIEGO, CA 92121

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay personas as well as scientists.

1. Registration Number: 93-R-0449

2. Number (six hundred sixty-eight) 668 of animals used in the study.

3. Species (common name) guinea pigs of animals used in the study.

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

Female Hartley guinea pigs are inoculated intravaginally with HSV-2, which will produce virus-induced lesions. The inoculation is accomplished using a moistened calcium alginate tipped swab soaked in an appropriate virus concentration. The swab is inserted into the vaginal tract rupturing the vaginal closure membrane and it is rotated approximately 10 times. Topical treatment is given three times daily beginning 24 hours after viral inoculation and is continued for 10-11 days. Topical treatment will be applied using a cotton swab both intravaginally and topically to the perineal skin of the guinea pig.

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.)

During all procedures, the guinea pigs are anesthetized using isoflurane to minimize both pain and stress. Topical analgesics cannot be used without compromising the results of the study, since topical treatments themselves are being investigated. Systemic analgesics such as NSAIDS or narcotic analgesics have effects on the immune system and would not be appropriate for use in this study because they will affect the immune system, which will then affect the reaction to the virus.

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 _____ CFR _____

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150 additional information

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0451 1153

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

Laris

XOMA Corporation
2910 Seventh St.
Berkeley, CA 94710

Tel:
(510) 644-1170

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)

804 Heinz Ave, Berkeley, CA

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	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	103	14	117
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.

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.

RECEIVED
NOV 30 2001
USDA, APHIS, AC
SACRAMENTO, CA

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 C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		28NOV01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 – HEADQUARTERS

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 93-R-0451

2. Number 14 of animals used in this study.

3. Species (common name) Rabbit of animals used in the study.

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

Rabbits are Catheterized in either the jugular vein and Carotid artery, or the femoral vein and femoral artery, followed by a prolonged Restraint in a Rabbit restraint upon awaking from anesthetic, while Cardiac parameters are monitored.

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)

Animals are provided with anesthetic and Topical/Systemic analgesic if needed for surgical procedures. It was felt by the IACUC that due to the Combination of discomfort post Surgically and Restraint time, this protocol falls into a Class E Category.

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 _____ CFR _____

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0464 **CUSTOMER NO.** 15322

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

WESTERN UNIVERSITY OF HEALTH SCIENCES
309 EAST SECOND STREET
POMONA, CA 91766-1854

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)*

HEALTH PROFESSIONS CENTER
POMONA, CA 91766-1854

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	4			34	34
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/31/2003

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 93-R-0464

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

Guinea Pigs (34)

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

Guinea pigs are guillotined to obtain brain tissues following the protocol recommended in the AVMA Policy on Euthanasia (2000).

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)

A review of the pharmacology of currently available anesthetics indicates that anesthetetics elevate prolactin levels (as well as other pituitary hormones) by a direct action on the hypothalamic A12 dopamine neurons that tonically inhibit prolactin release. The release of prolactin adversely affects the electrophysiological records of hypothalamic slices being studied in the protocol. Review of the current literature of acceptable means of euthanization conducted by the PI and reviewed by the IACUC determined that all chemical means of euthanization would adversely impact the physiologic processes being investigated. Guillotining by appropriately trained personnel was determined to the the least painful means of euthanization available to meet the requirements of the study.

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: CFR:

APHIS Form 7023 Additional Reported Sites

The following additional sites have been reported by the facility. The reported sites have not been verified by APHIS and have been provided by the facility solely for completeness of the APHIS Form 7023 Annual Reporting submission.

Registration Number: 93-R-0464
Customer Number: 15322
Facility: WESTERN UNIVERSITY OF HEALTH SCIENCES
309 EAST SECOND STREET
POMONA, CA 91766-1854

Site A Alumni Center Laboratories
Site A 309 East Second Street
Site A Pomona, CA 91766
Site B Health Professions Center
Site B 521 East Third Street
Site B Pomona, CA 91766

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0478 | CUSTOMER NO. 22163 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

OPTIMER PHARMACDEUTICALS, INC.
10110 SORRENTO VALLEY ROAD, STE. C
SAN DIEGO, CA 92121
(858) 909-0736

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)

10110 Sorrento Valley Road, Suite C

San Diego, CA 92121

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	0	110	0	68	178
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.

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		4/22/03

APHIS FORM 7023 (AUG (Replaces (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

OCT - 2 2003

ANNUAL REPORT OF RESEARCH FACILITY	Optimer Pharmaceuticals, Inc

Column E Explanation

1. Registration Number: 93-R-0478

2. Number of animals used in this study: 178 Total; 68 Category E

3. Species (common name) of animals used in this study: hamster

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

The animals were used in an experimental model of *Clostridium difficile*-Associated Diarrhea (CDAD). CDAD is a significant problem in hospitals and in long-term care facilities. *Clostridium difficile* is the most common cause of nosocomial diarrhea in developed countries: The organism accounts for approximately 20% of the cases of antibiotic-associated diarrhea, and for the majority of cases of antibiotic-associated colitis. Fifteen to twenty per cent of hospitalized patients may carry or acquire this organism; approximately 10% of that number develop CDAD, which can be fatal if untreated.

In 1977, a scientific team that included Optimer consultant Dr. Sherwood Gorbach identified *C. difficile* as the cause of the disease, and developed the hamster model of CDAD[1]. In this model, which has been used extensively by other investigators, hamsters are pre-treated with clindamycin to disrupt the normal gut flora, subsequently challenged with toxigenic *C. difficile*, and then treated with antibiotics.

[1]Infect. Immun 1978; 20(2):526-9

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.)

In the hamster model of CDAD, *Clostridium difficile*-infected animals that are untreated or treated with ineffective experimental antibiotics progress rapidly from apparent good health to death in a period of a few hours. In our implementation of this model, pain is managed by limiting its duration: Animals that are in distress or discovered moribund are humanely euthanized with CO_2 gas, in compliance with the recommendations of the AVMA Panel on Euthanasia (J. Am. Vet. Med. Assoc. 2000;218: 669-696). Investigators who regularly work with this model do not provide analgesia, as the literature documents that analgesia would either be ineffective or interfere with the experiment regardless which of the three major classes to which the drug might belong: (a) *opiates*—e.g. buprenorphine, which may be conveniently given to rodents, interferes with gut motility, while specific alterations in gut motility are features of this disease (other accessible opiates would react similarly); (b) *anti-inflammatory drugs*—NSAIDs, aspirin, or (to a lesser extent) acetaminophen would suppress the inflammation that is an essential feature of the disease; acute diarrhea, relapse of inflammatory bowel disease (IBD), microscopic colitis and acute pancreatitis may be induced by ingestion of standard NSAIDs; hemorrhage, a feature of CDAD, might be exacerbated by aspirin or NSAIDs ; (c) *peripherally-acting compounds* such as local anesthetics or antihistamines would be ineffective.

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

No federal regulations require this procedure.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 95-R-0002 CUSTOMER NO. 19

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF HAWAII AT MANOA
OFFICE OF THE CHANCELLOR
BACHMAN HALL, 2444 DOLE STREET
HONOLULU, HI 96822
(808) 956-7651

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)*

See Attached Listing

Refer to attachment (page 2)

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	—	—	—	—	0
5. Cats	—	1	—	—	1
6. Guinea Pigs	—	2	—	—	2
7. Hamsters	—	93	22	149	264
8. Rabbits	—	26	—	15	41
9. Non-Human Primates	23	—	—	—	0
10. Sheep	—	—	—	—	0
11. Pigs	—	—	—	—	0
12. Other Farm Animals	—	—	—	—	0
13. Other Animals					
Dolphins	—	5	—	—	5
False Killer Whale	—	1	—	—	1
Monk Seals	—	2	—	—	2

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 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/22/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

OCT 27 2003

The following sites have been reported by the facility.

Registration Number: 95-R-0002
Customer Number: 19
Facility: UNIVERSITY OF HAWAII AT MANOA
OFFICE OF THE CHANCELLOR
BACHMAN HALL, 2444 DOLE STREET
HONOLULU, HI 96822
(808) 956-7651

UNIVERSITY OF HAWAII AT MANOA
OFFICE OF THE CHANCELLOR
BACHMAN HALL, 2444 DOLE STREET
(MANY BUILDINGS)
HONOLULU, HI 96822

ANNUAL REPORT OF RESEARCH FACILITY - 2002-2003

Reporting Facility (This listing represents all locations where animals were housed or used in actual research, testing, teaching, or experimentation or held for these purposes.)

For the Reporting Period - **October 1, 2002 to September 30, 2003** the following locations (facilities and laboratories) were used by Registrant **95-R-0002**.

U of HI - Biomedical Sciences Building:
1960 East-West Road
Honolulu, HI 96822
County of Honolulu
Contact:
(808) - 956-8770

U of HI - Snyder Hall 5th Floor
2538 McCarthy Mall
Honolulu, HI 96822
County of Honolulu
Contact:
(808) - 956-8770

U of HI - Auxiliary Services Building
1951 East-West Road
Honolulu, HI 96822
County of Honolulu
Contact:
(808) - 956-8746

U of HI - Institute for Biogenesis Research
1960 East-West Road
Honolulu, HI 96822
County of Honolulu
Contact:
(808) - 956-8746

U of HI - Bekesy Laboratory of Neurobiology
1993 East-West Road
Honolulu, HI 96822
County of Honolulu
Contact:

U of HI - Kewalo Basin Dolphin Research Laboratory
1129 Ala Moana Blvd.
Honolulu, HI 96814
County of Honolulu
Contact:
(808) - 538-0067

U of HI - Woodlawn Small Animal Facility
2721 Woodlawn Drive
Honolulu, HI 96822
County of Honolulu
Contact:

U of HI - Marine Mammal Research Program
Hawaii Institute of Marine Biology
Coconut Island, P.O. Box 116
Honolulu, HI 96734
County of Honolulu
Contact:
(808) - 236-4001

U of HI - Waikiki Aquarium
2777 Kalakaua Ave.
Honolulu, HI 96815
County of Honolulu
Contact:
(808) - 923-9741

Column E Explanation (#1)

1. Registration Number: *95-R-0002 (Customer #19)*

2. Number of animals used in the study. *149*

3. Species (common name) of animals used in the study: *Hamsters*

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

One-hundred forty-nine (149) Golden Syrian Hamsters were used by one University of Hawaii (UH) Principal Investigator (PI) in the continuation of a study entitled "Effects of Novel Anti-Depressant Compounds in a Visible Burrow System". The PI's research investigates the effects of treatments of novel antidepressant compounds on chronic social stress and the behavioral and brain systems involved in defense and depression.

The PI explains that the study uses animal subjects for testing levels of aggression in a Resident-Intruder paradigm. In the paradigm, an intruder hamster is placed into the homecage of the resident. The model involves transient/distress to both the resident and intruder. Because hamsters, like other rodents, are territorial, the resident will protect its cage by engaging in defensive behavior. The PI explained that hamsters are an ideal model because these animals are the most frequently utilized species in studying vassopressin and aggression; therefore, the species behavioral profile in agonistic encounters is well documented.

A CRF (Corticosteroid Releasing Factor) is administered to the resident animals and the agent affects on aggressive behavior is assessed. The PI tested several proprietary compounds during the study.

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 would interfere with test results. (For Federally mandated testing, see Item 6 below).

Since the study involved the administration of the putative antidepressant in the intruder, the administration of anesthetics or pain-relieving drugs would interfere with the ability to effectively evaluate the compounds being tested by preventing normal patterns of behavior. In addition, the use of anesthetics in the intruder may have interfered with the response to the resident and further influence the behavior of the resident by providing an olfactory cue that may have functioned to reduce aggression. The PI affirmed that the aggressive behavior observed was considered to be relatively light and bites did not involve the breakage of skin of the intruder. The resident/intruder pairing last no more than a maximum of 15 minutes but terminated earlier if an animal subject incurred four bites before the end of the test.

6. What, if any, fedeal regulations require this procedure? Cite the agency, the code of federal regulations (CFR) title number and the specific section number (e.g., APHIS, CFR 113.102): *Not Applicable (N/A)*

Agency: *(N/A)* CFR: *(N/A)*

Column E Explanation (#2)

1. Registration Number: *95-R-0002 (Customer #19)*

2. Number of animals used in the study. *3*

3. Species (common name) of animals used in the study: *Rabbits*

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

Three (3) New Zealand White rabbits were used by one Principal Investigator (PI) in the continuation of a study entitled "Development of a MSP1-p42 Subunit Vaccine for Malaria". The objective of the research was to test a candidate malaria vaccine, that has been shown to have good antigenic properties and is produced at high levels for protective antibody response in animal host. One of the main objectives of this study was to compare the effect of several alternative adjuvants which are potential candidates for use in humans for their ability to elicit the desired immune response. Positive results from the immunization of rabbits would allow the recombinant malaria antigens to be advanced as a serious vaccine candidate to be later test in non-human primates

The PI explained that rabbits immunized with the candidate malaria vaccine combined with the proposed adjuvants to test for the ability to generate serum antibodies that are capable of killing malaria parasites in an in-vitro assay. The in-vitro assay has been shown to be a surrogate marker for in-vivo protective immunity against malaria infections.

The three rabbits assigned to the E pain and/or distress category are those animals that received Freund's adjuvant which is considered to cause some discomfort at the injection sites. The administration of Freund's adjuvant is being used as a control so that comparisons can be made to the other adjuvants being tested. If the experiments proved to be successful in identifying an adjuvant the provides results approximately equal to that elicited by Freund's treated animals, then the PI will no longer require the use of Freund's adjuvant as a control.

The rabbits that served as controls ***did not*** *appear to be in any distress during the study.*

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 would interfere with test results. (For Federally mandated testing, see Item 6 below).

If the rabbits that were treated with Freund's adjuvant were observed to exhibit behavior that was associated with pain and/or distress, the animals would have been removed from the study by the PI. ***The University attending veterinarian would have then administered pain-relieving drugs and medications.***

Additional justification why pain and/ or distress could not be relieved. Explanation why CFA is required in the study:

The PI explained that the objective of this project is to test a candidate malaria vaccine that has been shown to have good antigenic properties and is produced at high levels, for protective antibody response in animal hosts. One of the main goals of this study is to compare the effect of several alternative adjuvants that are potential candidates for use in humans for their ability to elicit the desired immune response. The strategy being employed requires screening of adjuvants in mice and rabbits, selecting an adjuvant

Column E Explanation (#2)

formulation that is suitable for human use, and then testing the selected adjuvant formulation in a relevant monkey challenge model. A successful outcome in a malaria challenge experiment with an adjuvant that is suitable for human use would be a major advancement in the field of malaria vaccine development.

The PI explained that the development of a malaria blood-stage vaccine faces two major obstacles. These are the lack of a established assay for assessing immunological relevance with out conducting a monkey challenge study and the only adjuvant that has been repeatedly demonstrated to result in a relevant immune response with candidate vaccines is CFA.

The work in this study is designed to identify an adjuvant formulation other than CFA for use in a malaria blood-stage vaccine containing a MSP-1 subunit antigen. The PI has chosen to utilize the ability to generate serum antibodies that are capable of killing malaria parasites in an in-vitro assay as the assay to screen various adjuvant formulations. This in-vitro assay has been shown to be a surrogate marker for in vivo protective immunity against malaria infections. CFA is the only adjuvant that has been demonstrated to reproducibly result in the generation of such serum antibodies. Therefore, in the experiments for screening adjuvants will need to include a group of animals that receive vaccine formulated with CFA to provide a standard to compare all other vaccine formulations. CFA is still widely used by malaria researchers. It is the PI's goal to identify an adjuvant to replace the use of CFA due to its tendency to cause pain and distress in experimental animals and that it cannot be used in humans.

The PI confirmed that none of the rabbits that served as controls, those receiving CFA appeared to be in any distress during the course of the studies. Furthermore, these studies have successfully identified an alternative adjuvant formulation and the PI will no longer use CFA adjuvant with MSP-1 subunit vaccine candidates.

6. What, if any, fedeal regulations require this procedure? Cite the agency, the code of federal regulations (CFR) title number and the specific section number (e.g., APHIS, CFR 113.102): *Not Applicable (N/A)*

Agency: *(N/A)* CFR: *(N/A)*

Column E Explanation (#3)

1. Registration Number: *95-R-0002 (Customer #19)*

2. Number of animals used in the study. *12*

3. Species (common name) of animals used in the study: *Rabbits*

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

Twelve (12) New Zealand White rabbits were used by one University of Hawaii (UH) Principal Investigator (PI) in the continuation of a study entitled "Immune Pathways as Prerequisite for Adjuvants' Efficacies". The overall goal of this study is to dissect the immunological requirements for adjuvant's efficacies. The PI largely uses mice that are genetically deficient in a number of selected immune mediators and evaluate the immunopotentiating activities of several non-toxic adjuvants in inducing antibody and cell mediated immune responses to a candidate malaria vaccine. The PI extended the evaluation of the efficacies of the adjuvants to different animal species. At this time rabbits were also used in the study. The PI justifies that a better understanding of the mode of action of adjuvants will allow rational design of the next generation of adjuvants with increased potency and further reduced toxicity

The twelve rabbits assigned to the E pain and/or distress category are those animals that received Freund's adjuvant which is considered to cause some discomfort at the injection sites. The PI affirms that currently Complete Freund's Adjuvant (CFA) is the only adjuvant that reliably generates a biologically active antibody response in rabbits using the candidate vaccine. Therefore, to compare the efficacy of different vaccines, the PI's research group required the use of CFA.

The rabbits that were treated with CFA ***did not*** *appear to be in any distress during the study.*

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 would interfere with test results. (For Federally mandated testing, see Item 6 below).

If the rabbits that were treated with CFA were observed to exhibit behavior that was associated with pain and/or distress, the animals would have been removed from the study by the PI. ***The University attending veterinarian would have then administered pain-relieving drugs and medications.***

Additional justification why pain and/ or distress could not be relieved. Explanation why CFA is required in the study:

The PI explained that adjuvants are once thought of as non-specific potentiators of immune responses. The PI claims there is mounting evidence that adjuvants can have effects on the quality of immune responses; namely, they can affect the specificity of immune responses. The PI's laboratory found that using CFA together with a malaria vaccine enables animals to develop specific anti-malaria antibodies that kill the malaria parasites. While other non-toxic adjuvants can induce antibodies to the malaria parasites, these antibodies have been do not kill the parasites. CFA is able to induce a special type of antibody that most other adjuvants cannot. One of the research objects is to replace CFA with other non-toxic adjuvants during immunization with malaria vaccines. Because the PI does not know what kind of antibody will kill the malaria parasites, they need to use CFA as a positive control adjuvant for the malaria vaccines. Therefore, if animals that receive CFA/malaria vaccines do not develop parasite killing

Column E Explanation (#3)

antibodies, the PI suspects that the vaccine itself has not been optimized. If other adjuvants in combination with malaria vaccines do not induce parasite killing antibodies, but, the CFA/malaria vaccine does, then the PI can conclude that the non-toxic adjuvants that are being tested are not efficacious. If this is the case, then the research will move on to test other non-toxic adjuvants.

6. What, if any, fedeal regulations require this procedure? Cite the agency, the code of federal regulations (CFR) title number and the specific section number (e.g., APHIS, CFR 113.102): *Not Applicable (N/A)*

Agency: *(N/A)* CFR: *(N/A)*

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 2150

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 14-V-003 #653

FORM APPROVED OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Dept. of Veterans Affairs National Headquarters
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)*

525 VA Medical Center
940 Belmont Street (Brockton Division)
Brockton, MA 02301

1400 VFW Parkway (West Roxbury Division)
West Roxbury, MA 02132

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			96 (WR Div)		96
9. Non-human Primates					
10. Sheep					
11. Pigs			4 (WR Div)		4
12. Other Farm Animals					
13. Other Animals					
Rats		36 (WR)	291 (BR Div) 320 (WR Div)		647
Mice			115 (BR Div) 473 (WR Div)		588
Opossums			6 (WR Div)		6

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
	ystem	11/14/02

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
14-V-004 #651

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
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)*

523 VA Medical Center
150 S. Hungington Ave., Boston, MA 02130

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			9		9
5. Cats			0		
6. Guinea Pigs			0		
7. Hamsters			0		
8. Rabbits			66		66
9. Non-human Primates			0		
10. Sheep			6		6
11. Pigs			0		
12. Other Farm Animals			0		
13. Other Animals					
Rats			40		40
Mice			573		573

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 *(Type or Print)*	DATE SIGNED
		1/14/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
16-V-002 # 454

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs
Research and Development Computing Center (151A)
103 South Gay Street, Room 400
Baltimore, MD 21202-4051

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)*

VA Connecticut Healthcare System (689)
~~950 Campbell Avenue~~
West Haven, CT 06516

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	9	0	9
9. Non-human Primates	12	0	26	0	26
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					
~~Mastomys~~	161	0	86	0	86

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		11-15-01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Contr
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 23-~~Y-002~~ #658 23-Y-0062

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Dept. 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)*

Dept of Veterans Affairs Medical Center
University & Woodland Avenue
Philadelphia, PA 19104

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	0	0	0	0	0
5. Cats	2	0	18	0	18
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	12	0	12
9. Non-human Primates	5	0	10	0	10
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 approriate 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 HEADQUARTES 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
		11/6/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

Chr L

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 21-V-002 #462

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Dept. of Veterans Affairs Natl. Headquarters
810 Vermont Ave., N.W.
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)*

V.A.W.N.Y. Healthcare System
3495 Bailey Avenue
Buffalo, New York 14215

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		16			16
6. Guinea Pigs					-
7. Hamsters					-
8. Rabbits		1	64		65
9. Non-human Primates					-
10. Sheep			17		17
11. Pigs			6		6
12. Other Farm Animals					
13. Other Animals					
Rats	316	938	128		1066
Mice	128	230	777		1192
Nude/Scid/KO Mice	238		348		348

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		11-15-01

APHIS FORM 7023 (Replaces VS FORM 16-23 (OCT 88), which is obsolete.)

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 2150

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 23-V-003 # 678

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs
Central Office
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)*

VA Pittsburgh Healthcare System
University Drive C

Pittsburgh, PA 15240

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			0		0
5. Cats					
6. Guinea Pigs		0			0
7. Hamsters					
8. Rabbits		24			24
9. Non-human Primates					
10. Sheep					
11. Pigs		0			0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		11/19/01

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
21-V-004 # 660

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Dept of Veterans Affairs Central Office
Vermont Avenue N.W.
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)*

VA New York Harbor Healthcare System

800 Poly Place Brooklyn NY 11209

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	0	0	1	0	1
5. Cats	0	0	0	0	0
6. Guinea Pigs	5	0	58	0	58
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	36	0	36
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Rats	25	0	343	0	343
Mice	227	0	220	0	220
Frobs	0	0	12	0	12

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
21-V-006

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*
Department of Veterans Affairs Central Office
810 Vermont Ave.
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)*

632 VA Medical Center, 79 Middleville Rd
Northport, NY 11768

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	0				0
5. Cats	0				0
6. Guinea Pigs	10		70		70
7. Hamsters	0				0
8. Rabbits	0				0
9. Non-human Primates	0				0
10. Sheep	0				0
11. Pigs			2		2
12. Other Farm Animals					0
13. Other Animals					
Mice	400	8920		23	8943
Rats	10		120	18	138

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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).

SIGN	E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
			12/30/00

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
21-V-007 #1165

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Control Off
810 Vermont Ave 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)*

VA Medical Center
800 Irving Ave
Syracuse, NY 13210

Department Of Lab Animal Resources
SUNY HSC 766 Irving Ave
Syracuse NY, 13210

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		22			22
7. Hamsters					
8. Rabbits					
9. Non-human Primates			4		4
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
RATS		81			81
MICE		1304			1304

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		11/14/9

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
21-v-008

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Dept. of Veterans Affairs
810 Vermont Ave., 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)*

528A8 Stratton VA Medical Center
113 Holland Avenue
Albany, NY 12208

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	29	0	414	0	414
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats	110	0	1077	0	1077
Mice	0	0	159	0	159

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		10/1/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FISCAL YEAR 2001

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 21-C-0014 (0047)

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

DEPARTMENT OF VETERANS AFFAIRS
CENTRAL OFFICE
810 Vermont Avenue, N.W.
Washington, D.C. 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)*

526- VA Medical Center
130 W Kingsbridge Road
Bronx, New York 10468

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	0	29	8	0	37
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	1	0	0	1
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	37	0	37
9. Non-human Primates	0	0	15	0	15
10. Sheep	0	0	2	0	2
11. Pigs	0	0	25	0	25
12. Other Farm Animals					
13. Other Animals					
14. Rats	0	0	208	0	208
15. Mice	0	10	181	0	191

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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.)

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 2150

See reverse side for additional information

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 34-V-002 #739

FORM APPROVED OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
810 Vermont Ave. 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)*

VA Ann Arbor Healthcare System (506)
2215 Fuller Rd.
Ann Arbor, MI 48105

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			65		
5. Cats			0		
6. Guinea Pigs			0		
7. Hamsters			0		
8. Rabbits			55		
9. Non-human Primates			28		
10. Sheep			2		
11. Pigs			13		
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, 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/14/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM OCT 88), which is obsolete)

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 2150

See reverse side for additional information

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. A 3493-01 41-V-0001

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

U.S. Dept. of Veterans Affairs Headquarters Office
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)*

VA Medical Center (151),
One Veterans Drive, Minneapolis, MN 55417

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	3	9	27		36
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		12	129		141
9. Non-human Primates	4	3	6		9
10. Sheep			33		33
11. Pigs			109		109
12. Other Farm Animals					
13. Other Animals					
Rats	258	116	2262		2378
Mice	94	213	2919		3132

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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 I - OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/15/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 42-V-003

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, Include Zip Code)*

VA Central Iowa Health Care System
3600 30th Street
Des Moines, Iowa 50320

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)*

555- Surgical Teaching Lab (STL)

October 2000 - September 2001

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	4		58		58
5. Cats	0		36		36
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats	6		38		38

RECEIVED
NOV 29 2001
USDA, APHIS, RAC, AC
SACRAMENTO, CA

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 HEADQUARTES 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
		10-25-01

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 2150.

DEC 15 2003

See reverse side for additional information.

1373

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 43-V-001

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
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)*

VA Medical Center (543), 800 Hospital Drive, Columbia, MO 65201

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					
Mice	0	1076	218	0	1294
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.

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 Lega

I certify that the above is true, corr

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NA	Print)	DATE SIGNED
			11-7-0

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

DEC 15 2003

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
43 V - 003

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*
Dept. of Veterans Affairs Headquarters
810 Vermont Avenue, N.W.
Washington, D.C. 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)*

Dept. of Veterans Affairs Medical Center
915 N. Grand Blvd., JC Division
St. Louis, MO 63106

Dept. of Veterans Affairs Medical Center
#1 Jefferson Barracks, JB Division
St. Louis, MO 63125

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	2				2
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
14. Mice	1,550	11,649			13,199
15. Rats		200	182		382
16. Frogs		18			18

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		10/7/03

APHIS FORM 7023
(AUG 91)

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

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

2003
ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 46-0001 (77)562

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

VA MEDICAL & REGIONAL OFFICE CENTER
2501 W. 22nd STREET
SIOUX FALLS, SD 57105

AT 1-15-04

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)*

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			15		15
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.

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 HEADQUARTES
(Chief Executive Officer or Legally E
I certify that the above is true, correct, a

ICIAL
ial)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & T	ICIAL *(Type or Print)*	DATE SIGNED
			10/23/03

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 2150.

DEC 4 2003

See reverse side for additional information.

Interagency Report Cont 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
47-V-001

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Headquarters
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)*

VA Medical Center (636)
4101 Woolworth Avenue
Omaha, NE 68105

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			13		13
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			12		12
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats	50	818	610		1,428
Mice		950			950

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
		11/3/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

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 2150

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 51-V-010 # 742

FORM APPROVED OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Headquarters
810 Vermont Avenue, N.W.
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)*

512 VA Maryland Health Care System
10 N. Greene Street
Baltimore, MD 21201

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	0	0	3,638	0	3,638
8. Rabbits	0	0	185	0	185
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 approriate 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).

C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/16/92

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150. 0010 See reverse side for additional information. 0013 Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

442

1. REGISTRATION NO.
51-V-010 & 51-V-013

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
810 Vermont Avenue, N.W.
Washington, D.C. 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)*

512 VA Medical Center
10 N. Greene Street
Baltimore, MD 21201

641 VA Medical Center
Perry Point, MD 21901

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	0	2,446	2,378	0	4,824
8. Rabbits	0	6	204	0	210
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 approriate 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 HEADQUARTES 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

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 52-V-003 #681

FORM APPROVED OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
810 Vermont Avenue
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)*

652 McGuire VA Medical Center
1201 Broad Rock Blvd.
Richmond, VA 23249

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			52		52
5. Cats			0		0
6. Guinea Pigs			0		0
7. Hamsters			0		0
8. Rabbits			75		75
9. Non-human Primates			0		0
10. Sheep			0		0
11. Pigs			0		0
12. Other Farm Animals			0		0
13. Other Animals					
Rats			727		727
Mice			127		127

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		10/31/91

FORM 7023 (AUG 91) (Replaces CT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 55V003 982

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

VA Medical Center
508 Fulton St.
Durham, N.C. 27705

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)*

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	1		(7) +6		13
5. Cats			(12) + 31		43
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			(4) + 2		6
9. Non-human Primates				(4)	4
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 approriate 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. ( ) 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 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 HEADQUARTES 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
		11/3/04

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete)

PART 1 – HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
56-V-002 #945

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*
Department of Veterans Affairs Central Office
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)*

534 VA Medical Center
109 Bee Street
Charleston, SC 29401-5799

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	27		56		56
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice	440	4,289	155		4,444
Rats	135	1,416	19		1,435

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		11/14/2

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 56-V-003 #986

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
810 Vermont Ave., NW
Washington, D.C. 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)*

WJB Dorn VA Medical Center
6439 Garners Ferry Road
Columbia, SC 29209-1639

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			104		104
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats		376	41		408
Mice		36	205		241

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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
		11/9/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
57-V-002

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Heatral Office
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)*

(509) VA Medical Center
1 Freedom Way
Augusta, GA 30904-6285

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	3	0	3	0	3
12. Other Farm Animals	0	00	0	0	0
13. Other Animals					
Rats	1046	0	845	0	845
Mice	932	0	656	0	656

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		11/14/91

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150.

DEC 0 2 2003

See reverse side for additional information.

Interagency Report Control 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 58-V-005 Cust. No. 933

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

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)*

VA Medical Center/546
1201 NW 16th Street
Miami, Florida 33125

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	1	3	0	0	3
7. Hamsters	0	0	0	0	0
8. Rabbits	2	14	0	0	14
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0 0	0
13. Other Animals					
Rats	28	1,673	180	55	1,908
Mice	368	550	29	0	579
Frogs	36	108	0	0	108

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		11-11-03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 – SECTOR OFFICE

The following excerpt from the Animal Component Of Research Program (ACORP) of a funded VA Merit Review program active at our facility is provided as an explanation of the procedures producing pain or distress in animals listed in Category E of the Annual Report.

All surgeries are done under anesthesia, and the animals are insensate to the procedures (Cat.D). With the excitotoxic pain model (QUIS surgery, all Cat. E), post-op analgesics have not been used, since they are known to intefere with the development of the outcomes to be examined. The same has proved to be true after transplantation of cell lines intra-spinally. Due to the nature of the excitotoxic injury, animals recover the next day without complications. On occasion, however, animals will develop excessive self-directed behavior, i.e., grooming, and should this become a problem, animals will be euthanized. Providing analgesia with such categories of drugs such as NSAIDS (anti-inflammatories), naracotic analgesics (morphine analogues), anti-convulsants or alpha-adrenergic analgesics are known to interfer with the mechanisms of pain being studied here (and treated with the cell therapy interventions). Any animal which develops signs of severe pain (vocalization, autotomy, lethargy, dull coat, aggressive response to mild stimuli, fighting in the cages, weight loss >10%) will be excluded from the study and humanely euthanized with a DVR cocktail overdose. Each animal will be observed twice daily after each surgery, with body weight measured weekly. Each animal will have a personal health record maintained, including observations and treatments, including euthanasia, for untoward behaviors or signs of pain/distress. Although the PI will be responsible for such health records, the actual surgeon performing all procedures will perform the observations, treatments, and keep all health records for inspection in the Behavior suite of Dr. Eaton, Miami VAMC Animal Facility.

Class of analgesic	**Justification for absence of use**
OPIOIDS	**may replace/interfere with alterations in the animals endogenous opioid system after injury; opioids are also known to participate in the secondary injury cascade, thereby exacerbating the extent of injury.**
ALPHA-2-AGONISTS	**may lead to long-term changes in adrenergic [redacted] receptor [redacted] (or others)/receptor desensitization which is an important component in the onset of chronic pain behaviors.**

LOCAL/TOPICAL ANESTHETICS	**may interfere with or block sodium channels/or their firing; this is especially true in the case of peripheral injury models, but may be acceptable in the spinal cord injury models (such as QUIS.**
NSAIDS	**may prevent the immune response associated with injury that leads to the development of pain, e.g., apoptosis; as a critical component of the injury process, these drugs would significantly confound the experimental objectives of the research (such as the loss of endogenous GABA interneurons after injury).**
SEDATIVES/TRANQUILIZERS	**they do not function as analgesics; may lead to weight loss, abnormal grooming.**
OTHERS: ketamine, GABA agonists, NMDA antagonists	**may interfere with the cellular mechanisms/interventions being evaluated, i.e., the imbalance of excitatory/inhibitory systems after injury and with interventions.**

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 2150

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

VA MEDICAL CENTER FOR ANNUAL REPORT
1201 NW 16th ST RESEARCH FACILITY
Miami, FL 33125 *(TYPE OR PRINT)*

1. REGISTRATION NO. 58-V-005 #933

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Dept. of Veterans AffairsaHeadquarters
810 Vermont Avenue, NW
Washington, DC 20420

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach adidditional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12. &/OR 13. Other *(List by species)*	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)
Dogs	12	0	0	0	0
Cats	0	0	0	0	0
Guinea Pigs	12	4	0	0	4
Hamsters	0	0	0	0	0
Rabbits	0	2	0	0	0
Non-human primates	0	0	0	0	0
Sheep	0	0	0	0	0
Pigs	0	0	0	0	0
Other farm animals	0	0	0	0	0
13. OTHER					
Mice	123	2207	409	0	2616
Rats	40	74	96	0	170
Frogs	30	150	0	0	150

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 car

CERTIFICATION BY HEADQUARTES 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
		11/3/91

APHIS FORM 7023A
(AUG 91)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 58-V-0007 #940

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

DEPARTMENT OF VETERANS AFFAIRS HEADQUARTERS
810 Vermont Avenue
Washington, D.C., 20520

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)*

North Florida/South Georgia Veterans Health System
Malcom Randall VA Medical Center (573)

1601 S.W. Archer Road
Gainesville, Florida 32608-1197

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	2	0	5	0	5
5. Cats	1	0	3	0	3
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	10	0	161	0	161
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Rats	42	0	1095	0	1095
Mice	100	200	2052	0	2252

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 HEADQUARTES 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
		11/9/01

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
61-V-003 # 936

FORM APPROVED
OMB NO 0579-0036

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)*

596 VA Medical Center
2250 Leestown Road
Lexington, KY 40511-1093

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			2		2
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	100	518			618
Mice	2493	4992			7485

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally ial Official)
I certify that the above is true, correct, 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/5/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO.
61-V-003

FORM APPROVED
OMB NO. 0579-0036

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

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12. &/OR 13. Other *(List by species)*	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)
Gerbils			150		150

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and comple

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		12/5/01

APHIS FORM 7023A
(AUG 91)

PART 2 - SECTOR OFFICE

DEC 0 2 2003

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 63-V-002 937

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs HQ
810 Vermont Avenue, NW
Washington, D.C. 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)*

VA Tennessee Valley Healthcare System
Nashville Campus (626)
1310 24th Ave. S. Nashville, TN 37212-2637

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	0	29	48	0	77
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice	0	2,746	6,023	136	8,905
Rats	102	171	320	108	599

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
		11/06/03

APHIS FORM 7023 (AUG 91) (Replaces VS (OCT 88), which is obsolete.)

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 63-V-002

2. Number 26 of animals used in this study.

3. Species (common name) rat-sprague dawley of animals used in the study.

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

REM Sleep Deprivation

Behavioral Test- Free-operant avoidance

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)

see attachment

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 N/A CFR N/A

REMSD have been found only to alter avoidance responding so the free-operant avoidance procedure is necessary. Pain cannot be relieved because the stimulation produced by the shock is the animal's motivation for lever pressing to avoid shock.

7. Expected Clinical Signs Of Pain/Distress:
   Please describe clinical signs to be expected. Indicate the severity and duration of each clinical sign, the frequency the animal will be monitored and when the pain will be eliminated or managed (euthanasia, drugs or withdrawal of painful stimulus). The committee must understand that the pain is the minimum needed for the shortest time possible, consistent with the experimental goals.

   a. **REMSD:** No anticipated clinical signs of pain/distress are anticipated given our previous use of this technique. However, if animals fall repeatedly into the water they will be removed from the experiment.
   b. **Free-operant avoidance:** No anticipated clinical signs of pain/distress are anticipated given our previous use of this technique. However, if an animal fails to avoid at least 75% of shocks for 5 sessions they will be removed from the experiment.

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 63-V-002

2. Number 100% (82) of animals used in this study.

3. Species (common name) Rats of animals used in the study.

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

Various tests of thermal and chemical pain sensitivity:

including hotplates, tail flick, escape task, feeding interference task, place preference task (all are variations on hotplate) and Formalin test.

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)

The purpose of all of the above tests are to find ways to decrease pain sensitivity without applying some uncomfortable stimuli, it is impossible to detect a decrease in pain sensitivity in response to our various selective neural lesions.

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 _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 63-V-002

2. Number 100% (136) of animals used in this study.

3. Species (common name) Mice of animals used in the study.

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

Hotplate, Tail flick (thermal pain tests), Chemical pain tests (capsaicin, Acetic acid, Formalin)

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)

The purpose of these experiments are to detect changes in pain sensitivity as a result of genetic manipulations. It would be impossible to identify genes that affect pain sensitivity without testing the responses of genetically altered mice to uncompfortable stimuli.

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 _____ CFR _____

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 63-V-002 937

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs HQ
810 Vermont Avenue, NW
Washington, D.C. 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)*

VA Tennessee Valley Healthcare System
Nashville Campus (626)
1310 24th Ave. S. Nashville, TN 37212-2637

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	0	29	48	0	77
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice	0	2,746	6,023	136	8,905
Rats	102	171	320	108	599

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		11/06/03

APHIS FORM 7023 (AUG 91) (Replaces VS (OCT 88), which is obsolete)

PART 1 - HEADQUARTERS

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 63-V-002

2. Number 26 of animals used in this study.

3. Species (common name) rat-sprague dawley of animals used in the study.

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

   REM Sleep Deprivation

   Behavioral Test- Free-operant avoidance

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)

   see attachment

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 N/A CFR N/A

Statement C: Justification for Type C Animal Use

(If this statement is blank, you may delete it)

Attach a **separate** Statement C for each species

1. Species: Sprague-Dawley Rat

*Procedures that may cause more than momentary or slight pain **must**, in their planning, involve consultation with a veterinarian trained in Laboratory Animal Medicine.*

Veterinarians, Dr. Joan Richerson and Dr. Greg Hanley, may be reached by calling the Division of Animal Care at 322-2231.

2. Which Veterinarian Have You Consulted? Joan Richerson
   Date Consulted: 12/02

3. List Procedures That Will Cause Pain That You Propose To Use:

   a. *REM sleep deprivation*: REMSD entails placing an animal on a 7 cm pedestal in an environment surrounded by 28 C water. Two pedestals are present to allow movement. Food and fresh water are available ad libitum. Animals will be exposed to REMSD for 48 hr.

   b. ***Free-operant avoidance***: Avoidance entails placing an animal in a conditioning chamber. While in the chamber a 1 mA shock of 0.5 sec duration is delivered every 5 sec. Each time a lever is pressed, the next shock is postponed for 20 sec. By intermittently pressing the lever an animal can avoid most, or all, shocks.

4. Alternatives To Painful Procedures:
   The Principal Investigator must provide a written narrative of the sources consulted to determine whether or not alternatives exist to procedures that may cause pain or

The minimal written narrative must include:
- **Databases searched** or other sources consulted,
- **Date of the search,**
- **Years covered by the search**, and
- **Key words or search strategy** used by the Principal Investigator when considering *alternatives* to the above listed procedures or descriptions of other methods. **This information should provide assurance that there are no alternatives available to the painful or distressful procedures listed above.** The Narrative should be such that the Institutional Animal Care and Use Committee can readily assess whether the search topics were appropriate and whether the search was sufficiently thorough.

From the USDA ***Animal Care Resource Guide*** -- Policy #12:
Consideration of alternatives to each procedure which may cause pain or distress must state sources consulted, such as Biological Abstracts, Index Medicus, Medline, the Current Research Information Services (CRIS), and the Animal Welfare Information Center (AWIC).

Reduction, **replacement**, and **refinement** (the three R's) must be addressed, not just animal replacement.

distress.

Please Provide Your Narrative Below:

We have conducted a literature review to determine if (a) an alternative non-animal model existed to study the questions proposed and (b) if we were inadvertently replicating work from another laboratory. The search was conducted on 1/2/02 and covered the dates from 1/1/1970 to 3/1/02. The databases searched were Medline and PsychLit. In addition, an independent review has been conducted using the Animal Welfare Center of the U.S. Department of Agriculture's AGRICOLA database.

a. **REMSD:** Keywords included alternatives, sleep deprivation, rapid-eye movement sleep deprivation, paradoxical sleep deprivation, flower pot technique, and pedestal-over-water method. No alternative procedures or models were found for studying the mechanisms of sleep deprivation, nor was there any evidence that we are proposing to replicate previous work. Reduction: 48 hr of REMSD has been the minimum level demonstrated to induce changes in negatively reinforced operant behavior. Replacement: No procedures were found that would replace 48 hr of REMSD using the pedestal-over-water method. Refinement: In order to reduce possible stress produces by placement on a pedestal via immobility, we will use two pedestals to allow animals free movement within the REMSD tanks.

b. **Free-operant avoidance.** Keywords included alternatives, active avoidance, negative reinforcement, free-operant avoidance, avoidance. No alternative procedures or models were found for studying avoidance reinforcement, nor was there any evidence that we are proposing to replicate previous work. Reduction: A reduction in the level of stimulation increases the amount of time the animal needs to establish a useable baseline. An increase in the level of stimulation decreases the amount of time the animal needs to establish a useable baseline. Our use of 1 mA shock for 50 min sessions seems to minimize the balance between shock intensity and session duration. Replacement: No procedures were found that would replace the free-operant avoidance method. Refinement: We believe that we are currently using the best balance between shock intensity and session length to minimize stress to the animal.

5. Results Of Search:
   _X_ No alternatives were found.
   ___ **Yes**, alternatives were found. **Explain** why they cannot be used below:

6. Justify No Pain Relief:
   Provide a scientific justification why drugs, which might alleviate pain, will be withheld. Document the rationale for this decision and provide references, if possible. This information is required in our annual USDA report and may be quoted directly from this protocol form.

REMSD have been found only to alter avoidance responding so the free-operant avoidance procedure is necessary. Pain cannot be relieved because the stimulation produced by the shock is the animal's motivation for lever pressing to avoid shock.

7. Expected Clinical Signs Of Pain/Distress:
   Please describe clinical signs to be expected. Indicate the severity and duration of each clinical sign, the frequency the animal will be monitored and when the pain will be eliminated or managed (euthanasia, drugs or withdrawal of painful stimulus). The committee must understand that the pain is the minimum needed for the shortest time possible, consistent with the experimental goals.

   a. **REMSD:** No anticipated clinical signs of pain/distress are anticipated given our previous use of this technique. However, if animals fall repeatedly into the water they will be removed from the experiment.
   b. **Free-operant avoidance:** No anticipated clinical signs of pain/distress are anticipated given our previous use of this technique. However, if an animal fails to avoid at least 75% of shocks for 5 sessions they will be removed from the experiment.

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 63-V-002

2. Number 100% (136) of animals used in this study.

3. Species (common name) Mice of animals used in the study.

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

   Hotplate, Tail flick (thermal pain tests), Chemical pain tests (capsaicin, Acetic acid, Formalin)

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)

   The purpose of these experiments are to detect changes in pain sensitivity as a result of genetic manipulations. It would be impossible to identify genes that affect pain sensitivity without testing the responses of genetically altered mice to uncompfortable stimuli.

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 _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 63-V-002

2. Number 100% (82) of animals used in this study.

3. Species (common name) Rats of animals used in the study.

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

Various tests of thermal and chemical pain sensitivity:

including hotplates, tail flick, escape task, feeding interference task, place preference task (all are variations on hotplate) and Formalin test.

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)

The purpose of all of the above tests are to find ways to decrease pain sensitivity without applying some uncomfortable stimuli, it is impossible to detect a decrease in pain sensitivity in response to our various selective neural lesions.

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 _____ CFR _____

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
61-V-003

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

VA Medical Center
1101 Veterans Drive
Lexington, Kentucky 40502

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)*

596- VA Medical Center
1101 Veterans Drive
Lexington, Kentucky 40502

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	4	4
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Mice	811	2326	2659	1438	6423
Rats	73	15	400	29	444

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 – SECTOR OFFICE

Pain Category E Justifications

Painful Procedures:

- Administration of chemotherapeutic agents (SC or IP) to reduce xenograft tumor size.
- Surgical excision of tumors with assistance of anesthetic

Endpoint requirements:

- 10% weight loss, poor coat skin condition, decreased in grooming, activity, appetite and/or behavior.
- Xenograft tumors exceeding 3200 cubic millimeters, showing ulceration to the skin surface, evidence of infection, or impaired mobility.

The use of pain relieving medications is not possible since normal course of tumor progression may be altered by treatment.

Painful Procedures:

- Bone marrow transplant recipients for the determination of graft versus host disease
- Leukemia survival studies
- Irradiation survival studies

Endpoint requirements:

Stress relief not possible because pain-relieving drugs may affect outcome of the disease process.

- 20% weight loss from pre irradiation weight
- Decreased activity, ruffled fur, or failure to groom.

VMU # 01-0026V, 04-0010V

Painful Procedure:

- Lethal or sub lethal total body irradiation (TBI)
- Tumor cells (Lewis Lung or A20 lymphoma cells)
- Combination of TBI and tumor cells

Endpoint requirements:

- Sub lethal TBI experiments will experience some discomfort and may have diarrhea
- Sub lethal TBI and tumor cells experiments will be euthanized prior to cancer related death at specific time points.
- Lethal TBI with/without radioprotective drug therapy will experience unavoidable distress prior to death.

Mice will be euthanized at selected post treatment time points. Any mice experiencing pain or unexpected discomfort will be euthanized immediately. Unexpected discomfort is exhibited by lack of grooming, decreased inquisitiveness, and 20% weight loss compared to pre irradiation weight.

The use of pain relieving medications is not possible since normal course of tumor or irradiation damage may be altered by treatment.

Painful Procedure:

- Simulating uncontrolled hemorrhagic shock (UHS) in battlefield conditions. Current medications to alleviate pain depress cognitive function as well as negatively affecting physiological responses to trauma. To measure analgesic properties of the proposed opioid, 2 analgesic assays will be used. The rat-tail flick reflex and the paw lift hotplate assay.
- Pain relieving drugs can't be used because it may depress pain models and cognitive function, which is what is being measured.

Endpoint Criteria:

- Decreased activity that affect locomotion and grooming patterns
- 10% weight loss from initial weight

VMU # 03-0002V

Painful Procedure:

- Surgery for catheter placement will have appropriate anesthesia; however, they will be bled from the femoral artery catheter to simulate rapid blood loss in a battlefield condition. Uncontrolled hemorrhagic shock occurs without immediate analgesia and appropriate fluid resuscitation; therefore, the study requires rapid blood loss until the blood pressure drops to 30mmHg.

- Fluid resuscitation will be initiated at 30mmHg with lactated ringers and opioid infusions via the femoral vein until the pressure is steady at 60mmHg.
- Analgesic models using Rat tail flick, hotplate assay, and Carrageenan Hyperalgesia assay.
- Thermal stress- Animals will be placed in 42 degree C incubator for one hour.

Endpoint Criteria:

- Pain relieving drugs cannot be administered because the animals must experience the desert battlefield conditions and pain associated with UHS to measure if lactated ringers vs. lactated ringers combined with the delta opioid is a better treatment plan.
- Decreased activity that affect locomotion and grooming patterns
- 10% weight loss from initial weight

Painful Procedure:

- Immunodeficient SCID mice are used as a source of Pneumocystis organisms because the fungi cannot be cultured. SCID mice die from a natural infection within 8 weeks of exposure, usually from severe inflammatory response. Weekly subcutaneous cortisone injections will be administered beginning 6 weeks post exposure.

Endpoint Criteria:

- To decrease the numbers of animals used for organism collection, the wait period must be prolonged to allow significant growth. The lungs will be harvested when it has a large lung burden (8 weeks post exposure).
- Mice will be euthanized if found moribund.

Painful Procedure:

- Examines the interaction of viral infection with graft vs. host disease.
- Any interference in disease progression will limit ability to obtain meaningful data.

Endpoint criteria:

- weight loss greater than 20%
- severe signs of graft vs. host disease including skin lesions, diarrhea, alopecia, and hunched posture.

Painful Procedure:

- Inoculation of Pneumocystis Carinii (PC) and cytomegalovirus (CMV) in dually infected animals will cause pain and distress during course of the infection.
- Administration of analgesics and anti-inflammatory agents may alter the host immune responses that are being investigated.

Endpoint Criteria:

- More than 20% basal weight loss at any time
- Showing signs of distress: hunched posture, failure to groom, labored breathing, and lack of activity for 3 days.
- Moribund or fail to respond to external stimuli.

Painful Procedure:

- Interactions between a cytomegalovirus (CMV) and allogenic immune responses that ultimately result in disease.
- Total Body Irradiation (TBI) to eliminate hematopoietic cells.
- IV injection of Bone marrow cells-Under anesthesia mice will receive retro orbital IV injections of bone marrow and splenocytes. These mice will develop either graft vs. host disease and/or CMV.
- Administration of analgesics is not possible because it may alter the natural host responses and disease progression.

Endpoint Criteria:

- Appear moribund or in clinical distress
- 20% weight loss
- loss of inquisitiveness, lack of mobility, hunched posture, severe diarrhea, or severe skin lesions

Painful Procedure:

- Tissue cages previously surgically implanted will be infected with S. Aureus to determine growth characteristics of bacteria in vivo. These animals will not receive antibiotics.

Endpoint Criteria:

- Pain and distress will be relieved as much as possible during sampling procedures with the use of anesthetics and analgesics. It will not possible to relieve all pain and distress associated with the infection.
- If animal is in obvious pain, becomes anorexic, develops diarrhea, or exhibits greater than 10% weight loss for more than 2 days, it will be euthanized.
- All animals will be euthanized after sampling endpoints, no more than 10 days.

DEC 07 2004

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 2150.

See reverse side for additional information. 937

Interagency Report Cor 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 63-V-002

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Headquarte
810 Vermont Avenue, N.W.
Washington, D.C. 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)*

VA Tennessee Valley Healthcare System

Nashville Campus (626)
1310 24th Ave. S., Nashville, TN 37212

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		2	20		22
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Nonregulated:					
Mice	63	4,302	4,081	174	8,557
Rats	98	78	454	82	614

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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
		11-16-04

APHIS FORM 7023 (AUG 91) (Replaces A 18-23 (OCT 88), which is obsolete.)

PART 1 – HEADQUARTERS

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A column **E** explanation must be written so as to be understood by laypersons as well as scientists.

1. Registration Number: 63-V-002

2. Number of animals used in this study. 82

3. Species (common name) of animals used in the study. Rats

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

   Thermal sensitivity testing using hotplates at 44C, 47C and 52C. Cut-off times are provided for each temperature to prevent tissue damage, but rats will undeniably experience some degree of discomfort that cannot be relieved by drugs if meaningful results are to be obtained. Operant escape from thermal plates at .3, 38, 44, 47C; animals are allowed free access to a non painful alternative. Algesic chemical sensitization by intra-plantarformalin and topical application of capsaicin also produce nocifensive behaviors for 90 and 5 minutes respectfully. Surgical procedures: Lumbar intrathecal delivery of targeted toxins or drugs.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods of means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

   When the object of the research is to study pain perception, there is no alternative that does not involve some discomfort to the experimental subjects, animals or human. Most of the procedures being used in the present proposal involve significantly less intense pain stimuli than are routinely used in the great majority of published reports. The operant task minimize suffering by always allowing animals free access to a part of the test chamber that is at room temperature or cool. All surgical procedures are carried out using standard anesthesia and post-op care to minimize discomfort.

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 _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A column **E** explanation must be written so as to be understood by laypersons as well as scientists.

1. Registration Number: 63-V-002

2. Number of animals used in this study. 159

3. Species (common name) of animals used in the study. Mice

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

   Thermal sensitivity testing using hotplates at 44C, 47C, and 52C. Cut-off times are provided for each temperature to prevent tissue damage, but mice will undeniably experience some degree of discomfort that cannot be relieved by drugs if meaningful results are to be obtained. Operant escape from thermal plates at .3, 38, 44, 47C; animals are allowed free access to a non painful alternative. Algesic chemical sensitization by intra-plantar formalin and topical application of capsaicin also produce nocifensive behaviors for 90 and 5 minutes respectfully.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods of means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

   When the object of the research is to study pain perception there is no alternative that does not involve some discomfort to the experimental subjects, animal or human. Most of the procedures being used in the present proposal involve significantly less intense pain stimuli than are routinely used in the great majority of published reports. The operant tasks minimize suffering by always allowing animals free access to a part of the test chamber that is at room temperature or cool.

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 _____ CFR _____

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A column **E** explanation must be written so as to be understood by laypersons as well as scientists.

1. Registration Number: 63-V-002

2. Number of animals used in this study. 15

3. Species (common name) of animals used in the study. Mice

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

   Aggression toward conspecific. Ten minute tests of the degree to which a Particular mouse will engage in aggression toward another mouse. Referred to as the "resident-intruder" model.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods of means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

   Animals need to be ambulatory to become aggressive or receive aggression from Another mouse.

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 _____ CFR _____

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
63-V-002 #937

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Headquarters
810 Vermont Avenue, NW
Washington, D.C. 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)*

VA Tennessee Valley Healthcare System
Nashville Campus (626)
1310 24th Avenue South Nashville, TN 37212-2637

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	0	0	280	0	280
7. Hamsters					
8. Rabbits	0	70	25	0	95
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice	0	2456	2869	0	5325
Rats	0	449	624	266	1339

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		11/14/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 63-V-0003 #1938

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA. Include Zip Code)*

Department of Veterans Affairs Central Office
810 Vermont Avenue NW
Washington, D.C. 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)* 614

Memphis, Tn

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	12	0	12
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0
14. Rats	0	0	4	0	4
15. Mice	0	766	1015	60	1841

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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.C ITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/17/01

APHIS FORM 7023 (Replaces VS FORM 18- (OCT 88), which is obsolete)
(AUG 91)

PART 2 - SECTOR OFFICE

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 74-V-007

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

VA Medical Center
6010 Amarillo Blvd., West
Amarillo, Texas 79106

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)*

504 VA Medical Center, Amarillo, Texas

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			6		
5. Cats			7		
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		32			
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

RECEIVED
NOV 29 2001
USDA, APHIS, PEAC, AC
SACRAMENTO, CA

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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
		9/27/01

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 2 - SECTOR OFFICE

288

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

DEC 11

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
74-V-009

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
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.)

671

FACILITY LOCATIONS *(Sites)*

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

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			15	60	75
8. Rabbits			41		41
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats		198	36	397	631
Mice	8523	4604	4342	9076	18022

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 *(Type or Print)*	DATE SIGNED
		11/14/00

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

PART 1 - HEADQUARTERS

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 2150. See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

DEC 11

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
74-V-009

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
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.)

671

FACILITY LOCATIONS *(Sites)*

South Texas Veterans Health Care System
Audie L. Murphy Division

7400 Merton Minter Blvd.
San Antonio, TX 78284

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			15	60	75
8. Rabbits			41		41
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats		198	36	397	631
Mice	8523	4604	4342	9076	18022

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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
		11/14/00

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

2003

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
74-V-011 1350

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420

AF 1-16-04

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.) VA Medical Center (580/151), 2002 Holcombe Blvd., Houston, TX 77030

FACILITY LOCATIONS *(Sites)*

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			15		15
5. Cats		43			43
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		4			4
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 approriate 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		1/29/03

APHIS FORM 7 (AUG 91)

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

PART 1 – HEADQUARTERS

DEC 1 0 2003

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 2150.

See reverse side for additional information

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 85-V-001

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
810 Vermont Avenue N.W.
Washington, D.C. 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)*

501 New Mexico VA Health Care System
~~1501 San Pedro Dr. S.E.~~
Albuquerque, NM 87108

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	7	0	103	0	103
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	6	0	6
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	196	0	196
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.

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
		10/29/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

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 2150.

DEC 1 0 2003

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 82-V-001

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs
VACO
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)*

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		26			26
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.

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	DATE SIGNED
	10/27/03

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

PART 1 – HEADQUARTERS

DEC 07 2004

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 2150. See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
82-V-001

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs
VACO
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)*

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	23	17		1	18
9. Non-human Primates					
10. Sheep			35		35
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats	12	18	78		96
Mice		22		76	98

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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
(AUG 91)

(Replaces VS FORM 16-23 (OCT 88), which is obsolete.)

DEC 13 2004

Investigator:

Protocol #: (b)(4)

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

1 rabbits

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 2150.

See reverse side for additional information.

Interagency Report Control No. 0580-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

"A" type 02/15/05

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 82-V-001 Cust # 1314

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs
VACO
810 Vermont Avenue NW
Washington, DC 20420

Email change per me
202-336-5[illegible] (VACO?)
208-422-1000 (Boise)

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.)

208 422-1100 is # for IACUC Director

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				COPY FOR YOUR INFORMATION	
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					
Rats	12	13	78		86
Mice		22		76	98

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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)

DEC - 1 2004

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 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

Amat # 1314
5764 #1
82-V-0001

Investigator:

Protocol #: (b)(4)

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

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.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
93-V-003

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs Central Office
810 Vermont Avenue, N.W.
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)*

VA Palo Alto Health Care System (640)
3801 Miranda Avenue
Palo Alto, CA 94304

*Per phone communication between Dr. Garland & Stacey Moeder of Res., on 5/28/04, mice & rats are laboratory spp. & not regulated.

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		7	53		60
9. Non-human Primates					
10. Sheep					
11. Pigs			36		36
12. Other Farm Animals					
13. Other Animals					
Mice	2100	4700	2100	100	6900
Rats		330	650	470	1450

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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
		11/17/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 – HEADQUARTERS

VA Palo Alto Health Care System 2003

The following report describes and justifies all category E procedures conducted at the Veterinary Medical Unit at the VA Palo Alto Health Care System

For Animal Protocol entitled " Injury Induced Facilitated Neurogenic Inflammation":

For the sciatic nerve transection rat model:
We will use the rat model, which we have already described in over a dozen publications. Under isoflurane anesthesia the right sciatic nerve is surgically exposed just distal to the trochanter and transected with 1 cm of the distal stump removed. The skin is then closed with wound clips. Sham operated animals undergo skin incision without nerve dissection. These animals exhibit heat and mechanical hyperalgesia and mechanical allodynia over the hindpaw, which lasts for at least 8 weeks. We will keep these rats alive for 12 weeks, then euthanize them. This model is approved for use in other experiments in the current ACORP KIN0012Newrat. These animals are all category E.

For the healed tibial fracture model:
We propose to use a rat tibial fracture model treated with intramedually nailing and cast immobilization for 4 weeks, after which tibial union occurs and under pentobarbital anesthesia the intramedullary nail and cast are removed [3,6].Under pentobarbital (50 mg/kg, Lp.) anesthesia an 18 G cannula is inserted through the anterior tibial plateau into the meduallary canal. An Intramedullary nail (25 G stainless steel wire) is inserted into the tibia via the 18 G cannula, the cannula is removed, the nail cut, the skin closed with 1 stitch, then the tibia shaft is fractured with a special forceps, the rotation of the limb corrected by the alignment of the foot and thigh, then the limb is enveloped with tube gauss and wrapped with fiberglass casting tape from the knee to the calcaneus. To prevent the rats from gnawing off the cast an aluminum wire screen is wrapped around the cast and attached by wires passed through small holes at the edge of the fiberglass cast. For the first 2 days post-operatively the rats will receive analgesic medication (butorphanol 1 mg/kg s.c. twice a day). We will keep these rats alive for between 6 -24 weeks depending on the experiment, then euthanize them.

Justification: To investigate the neurogenic mechanisms of osteopenia after trauma we need to utilize these injury rat models. Any analgesic treatment that reduces nociceptive neuron firing may also impair the development of neurogenic osteopenia in these rat models, which are the critical outcome measure for these investigations. It is necessary to use 24 week survival times after injury in some of these experiments because these are models for a human condition of chronic osteopenia, and to validate these models of CRPS we need to confirm that the natural history resembles the chronic human state.

For Animal Protocol entitled
" HPA Axis/DA Interactions in Psychotic Depression":

For rat models to investigate HPA influence on central dopaminergic activity:
Mild stressors, such as low intensity foot shock, 24-hour food and water deprivation and physical restraint, are known to selectively stimulate dopaminergic metabolism in the medial prefrontal cortex. To investigate the paradigm, the animals are placed in a 7 cm diameter Plexiglass restraining tube (or plastic coated wire mesh tube for microdialysis studies) and confined for 30-120 minutes. For examination of the sustained effect of stress, animals will be confined for 6 hours per day for 21 days. Animals will be exposed to low ambient temperature (40 degrees Fahrenheit) to raise levels of costicosterone and prefrontal cortical DA release. The rats will be housed in a cold room with adequate ventilation and with bedding changed daily (to protect their feet) for 8-10 hours per day for 21 days.

Justification: Animals involved in prolonged physical restraint will be observed at half-hour intervals during the restraint period and receive daily health checks. The size of the tubes is adjusted for larger animals so the tubes are small enough to not allow them to turn around but big enough to allow unrestrained respiration and movement. The restraining tubes are commercially available devices used to assist in performing injections, sampling, etc. No direct physical pain will be involved. Animals housed in the cold room will be visually inspected every 4 hours and daily health checks will be performed by the investigators.

For Animal Protocol
entitled " The Roles of Heme Oxygenase in Pain":

For the animals involved in Partial sciatic nerve ligation:
Some rats will have ligation of approximately 1/3 of a single sciatic nerve in a brief (<10min) procedure. While the skin incision only needs to be about 1-1.5 cm and dissection of tissue is minimal, it is expected that over a period of 1-3 days rats will develop hypersensitivity to thermal and mechanical stimuli applied to certain parts of the animal's hind paw.
Justification: This model represents an improvement over previous models in which autotomy and pressure ulcers were common. The partially ligated animals do not show these behaviors and gain weight at the same rate as sham operated ones. There are no spontaneous pain behaviors like licking or biting of the affected paws. Thus the ligation provides a modest but useful sensitized state. Any animals showing frank neurological injury (weakness), spontaneous evidence of ongoing pain or illness will be euthanized.

For animals involved in Formalin testing:
In this protocol the injection of 50 ul of up to 5% formalin subcutaneously in a single rat hind paw causes approximately 45 minutes of behaviors like flinching, licking and biting of the hind paw presumably related to pain.
Justification: Since pain and the ability of various agents to block that pain is what is under study, no additional analgesics are used. Rats are used a single time for this assay, then are euthanized.

For the animals receiving CFA injection:
Animals injected subcutaneously in a single hind paw with 50ul CFA will, over a period of 24 hrs, develop an inflammatory reaction characterized by swelling of the affected paw as well as thermal hyperalgesia and mechanical allodynia.
Justification: There animals continue to gain weight and do not show spontaneous pain behaviors over the first 1 weeks or so. Beyond this point the animals develop systemic illness, which is why all rats will be tested and sacrificed within 7 days of injection in our protocols.

For the animals undergoing hind paw incision:
A 1 cm incision is made in a single hind paw while the animal is under anesthesia. The sensitivity of the area surrounding the incision to thermal and mechanical stimuli is followed for a period of up to 1 week.
Justification: While the animals continue to gain weight and seldom show spontaneous pain behaviors, no specific analgesics other than the ones under study will be used. Infections have not been observed in animals used under this protocol to date. We will be able to complete our experiments within 1 week of incision.

For Animal Protocol entitled
" Function and Dysfunction of Immediate Filaments in the Digestive System"

For animals receiving choline-deficient ethionine-supplemented diet feeding and caerulein injection:

It is possible that animals receiving the treatments that can cause pancreatitis (choline-deficient ethionine-supplemented diet feeding, and caerulein injection) will experience some discomfort due to the pancreatitis, and some may even die. In order to minimize this discomfort we will add to their drinking water 10% sucrose and also a pancreatic enzyme supplement to help with digestion. In humans, pancreatic enzyme supplementation is extremely beneficial in helping with digestion (due to the pancreatic insufficiency caused by pancreatitis) and can also help alleviate any abdominal pain caused by pancreatitis. In addition, mice will be monitored daily for weight loss or inability to thrive and if it appears that they are unable to eat or drink they will be euthanized by CO2 inhalation. Due to the potential of liver toxicity the high susceptibility to liver injury of these mice, which would add a confounding variable make our results uninterpretable, we will not administer any analgesics and feel that the administration of the enzyme supplementation and the monitoring for discomfort should be sufficient. The injury occurs primarily in young females for unknown reasons (see "Experimental Pancreatitis" Curr Opin in Gastroenterology 9:752-759, 1993). We specifically want some measurable lethality in order to test if the changes in our proteins are protective from injury/lethality of if they predispose to further injury/lethality. Depending on the change in our proteins we have seen either increased or decreased protection from liver injury. Hence, the same trends may occur in the pancreas which is a question we hope to address.

Justification: In order to minimize the discomfort due to pancreatitis, we will add to their drinking water 10% sucrose and also a pancreatic enzyme supplement to help with digestion. In humans, pancreatic enzyme supplementation is extremely beneficial in helping with digestion (due to the pancreatic insufficiency caused by pancreatitis) and can also help alleviate any abdominal pain caused by pancreatitis. In addition, mice will be monitored daily for weight loss or inability to thrive and if it appears that they are unable to eat or drink they will be euthanized by CO2 inhalation.

For Animal Protocol entitled
"Mechanisms for Tolerance to Actions of Alpha 2 Agonist"

For animals participating in Dexmedetomidine Withdrawal studies:
Tolerant mice will be given an a2 antagonist to cause a period of mild withdrawal (piloerection, twitching, jumping, salivation, pink ears). They will be sacrificed immediately afterward.

Justification: Animals undergoing morphine withdrawal are certainly distressed. Physiological (BP/heart rate) and behavioral (flapping/jumping/chattering) observations support this. The effects are transient after naloxone injection, with all measurable indices of distress being normal within 90 minutes. The overall degree of distress would be in the moderate category. From my discussions with David Clark he feels that there is no reason that he knows of that these animals would need to be sacrificed simply for compassionate reasons; animals off all drugs should recover fully. He sees no reason that the animals could not be used for other purposes once recovered.

For animals participating in Opiate Withdrawal studies:
Mice will be given morphine for 5 days then a challenge dose of naloxone will be administered to elicit opiate withdrawal behavior. The behavior of the animals will be monitored for signs of wet dog shakes, teeth chattering, diarrhea, micturition, piloerection, body shakes, running, paw tremors, and jumping for one hour after naloxone administration. Dr. David Clark, who routinely uses this protocol for his own work, will assist us in these studies.

Justification: Animals undergoing α_2 agonist withdrawal experience a milder withdrawal syndrome. Blood pressure and heart rate are elevated and they exhibit twitching jumping and occasionally seizures. The effects are transient after antagonist injection, with all measurable indices of distress being normal within 30 minutes. The overall degree of distress would be in the moderate category. The purpose of the withdrawal studies is to understand what brain regions are activated during withdrawal. Any intervention would very likely distort or invalidate the results

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-V-004 Cust # #1323

FORM APPROVED
OMB NO. 0579-0036

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

"A" by K. Garland 01/18/05

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.)

858
Call 552-8585 X3201 FACILITY LOCATIONS (Sites)

064- VA San Diego HealthCare System
3350 La Jolla Village Drive
San Diego, CA 92161

COPY FOR YOUR INFORMATION

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			3		3
6. Guinea Pigs			110		110
7. Hamsters					
8. Rabbits			1013	52	1065
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Opossum			14		14

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGN
	DEC - 1 2004	12/2/04

2004 Annual Report of Research Facility
664-VA San Diego Healthcare System

COPY FOR YOUR INFORMATION

RE: 93-V-004 Category E Studies

Two VASDHS IACUC approved protocols involve category E studies in Rabbits. These studies are conducted in accordance with all USDA, NIH and AAALAC, International guidelines and policies for the humane care and use of research animals.

The two studies identified as USDA category E involve well documented stroke models (cerebral ischemia and spinal cord ischemia) in rabbits. Stroke is produced either by injecting blood clots into the carotid artery (cerebral ischemia) or occlusion and reperfusion of the aorta (spinal cord ischemia). It should be noted that procedures to gain access to these vessels are performed under general anesthesia using aseptic technique. These surgical procedures are considered USDA category D procedures. Animals are allowed to fully recover from anesthesia prior to inducing the ischemic condition. The applicable ischemic condition is induced in awake rabbits placed in a standard rabbit restrainer. Although stroke is reportedly not painful in humans, it has the potential of being distressful, if severe. It is for this reason that these studies are identified as USDA category E studies. The animal models used in these studies have previously been used to develop the only FDA-approved treatment for stroke. In order to develop treatments, it is necessary to use a model system that accurately reproduces human stroke.

Following induction of the ischemic condition the animals are kept in the lab under close observation for at least 2 hours. A post-procedure behavioral scale (scaling 0-5) is used when monitoring the animals to rate the severity of the stroke. If it is determined that the severity of stroke is such that there is a potential that animals may not be able to eat or drink or if they may be in pain or distress, per the objective scoring behavioral scale, they are euthanized. Animals are monitored and evaluated daily by veterinary and laboratory staff utilizing the post-procedure behavioral scale and ensuring animals are able to eat and drink.

The main purpose of these studies using both the rabbit spinal cord ischemia and cerebral ischemia models is to develop new and effective treatments for ischemic injuries. Novel targets for therapeutic intervention include neuroprotection with compounds that reduce the inflammatory cascade and apoptotic mechanisms, including non-steroidal anti-inflammatory drugs, cyclo-oxygenase inhibitors (COX-2) and platelet-adhesion antagonists. We are also focused on early inhibition of the ischemic cascade and are studying compounds that reduce excitotoxicity and inhibit the deleterious effects of free radicals.

Typically, two classes of compound are used as pain-relievers in experimental animals. They include morphine analogs and NSAID's. Neither class of compound can be used in our experimental ischemia studies for many reasons, including their ability to confer neuroprotection via a variety of mechanisms and their ability to reduce inflammation. Since we are actively developing novel thrombolytics for the treatment of acute ischemic stroke compounds that affect blood chemistry especially the clotting mechanisms (e.g. aspirin), will interfere with the assessment of thrombolytics. A brief review of the scientific literature shows that simple compounds such as aspirin confer neuroprotection in models of CNS disease (Teismann and Ferger. Synapse 39: 167-174, 2001; Grilli et al., Science 274: 1383-1385; Vartiainen et al., J. Neurochem. 82: 329-335, 2002). Moreover, other aspirin-like platelet inhibitors can reduce ischemic brain damage (Moriguchi et al., JPET 308: 1094-1101, 2004). Historically, morphine and its analogs including buprenorphine have been known to be neuroprotective (Mastronardi and Cafiero, Minerva Anesthesiol. 67:332-7, 2001). The authors point out that that delta-opiate receptor compounds confer a preconditioning-like protective effects against myocardial ischemia mu-opiate and kappa-opiate receptors are involved in ischemic preconditioning against seizures in the brain. Moreover, a recent publication showed that treatment of rats with buprenorphine reduced lesion-induced cell death (Ozden et al., J. Neurotrauma 21: 73-82, 2004).

Anesthetics that interact or regulate potassium channels in the CNS play an important role in neuroprotection against brain and spinal cord ischemia (Heurteaux et al., EMBO J. 2004 Epub). Currently, there is literature showing that reducing body temperature (hypothermia) by 1 or more degrees may be neuroprotective (Smith J. Vasc. Interv. Radiol. 15:S3-12, 2004). Since many anesthetics reduce body temperature, it is likely that neuroprotection will be observed in our ischemia models. Animals are allowed to recover from anesthetic prior to producing stroke because of these anesthetic and hypothermic effects and in order to have a more relevant model by producing stroke in an awake animal.

2004 Annual Report of Research Facility
664-VA San Diego Healthcare System

RE: 93-V-004 Category E Studies

COPY FOR YOUR INFORMATION

Taken together, the scientific literature clearly shows that systemic intervention with analgesics and/or anesthetics in our models may obscure and interfere with the studies of new therapeutics to treat spinal cord ischemia and cerebral stroke. In both the rabbit spinal cord ischemia and brain ischemia models, there is a very low incidence of pain and/or distress. A typical study requires the use of 20-24 rabbits based upon power analysis calculations in order to complete a quantal analysis curve. Therefore, a complete study, including 3-4 durations of ischemia or treatment groups, required approximately 80 rabbits. Historically, approximately 20% are euthanized within the first two hours due to severity of the stroke (3-5 on our scoring scale). We have found that out of every 80-100 rabbits used according to the approved protocols, 4-5 rabbits must be euthanized after the first two hours and before the completion of the study due to severity of stroke and/or potential distress. Of the 1028 rabbits used for these studies during this reporting cycle 52 animals were humanely euthanized due to severity of stroke and/or potential distress and are reported in the 2004 USDA Annual Report as category E.

DEC 07 2004

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
93-V-004

FORM APPROVED
OMB NO. 0579-0036

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 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			3		3
6. Guinea Pigs			110		110
7. Hamsters					
8. Rabbits			1013	52	1065
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
[illegible]um			14		14

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)
DEC 13 2004
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		12/9/04

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 2150.

DEC 1 0 2003

See reverse side for additional information.

Interagency Report Control I
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
93-V-004

FORM APPROVED
OMB NO 0579-0036

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 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					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					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 HEADQUARTES 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)

SIGNATU L	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/28/03

APHIS FORM (AUG 91)

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

PART 1 - HEADQUARTERS

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 2150. See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
93-V-007

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Department of Veterans Affairs
810 Vermont Ave, N.W.
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)*

#600 - VA Long Beach Healthcare System
5901 E 7th Street
Long Beach, CA 90822

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			94		94
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats	62	688	927	552	2229
Mice	27	468	24	11	530

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 [illegible] Official)

I certify that the above is

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	OFFICIAL *(Type or Print)*	DATE SIGNED
		10/28/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 – HEADQUARTERS

Explanation of Category E:

Rabbits

PI: Haake
Protocols:

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:
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:

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.

PI: Tache
Protocol:
Number of animals under Category E: 30
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.

PI: Wasterlain
VA Merit Review # 9711-041
NIH/UCLA grant # 12105-02
Number of animals under Category E: 423
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.

PI: Yang
VA protocol
UCLA ARC # 2002-032-02
Number of animals under Category E: 10
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.

Mice

PI: Haake
Protocol #:
Number of animals under Category E: 24
Procedures involving 24 mice fall into Category E because of immunization with adjuvant, which is required for adequate B cell production.

PI: Mayer
Protocol:
Number of animals under Category E: 13
The mice listed under Category E were subjected to chemical stimulation of the colon as described in protocol entitiled "Modulation of stress-induced pain response in mice" (VA project 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:

Number of animals under Category E: 40
40 mice are listed under Category E for Protocols . In the mouse model of experimental pancreatitis (#0111-042), high doses of cerulein (an analogue of CCK), given as intraperitoneal ourly injections, cause acute pancreatitis. In Protocol the animals receive either intraperitoneal injections of cerulein or vehicle every hour for 7 hours.

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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 23-V-0005

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

Dept of Veterans Affairs
Research + Development Computing Center
103 South Gay Street - 4th Floor, Room 400
Baltimore MD 21202-4051

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)

VA Loma Linda Healthcare System
11201 Benton St., Loma Linda CA 92357

COPY

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	1	41			41
9. Non-human Primates					
10. Sheep				Correction:	
11. Pigs				See attached report	
12. Other Farm Animals				dated 30 June 04	
13. Other Animals					
Chinchillas			30	~~40~~ 60	90

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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
		11/14/03

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which obsolete.)

JUL 8 2004

PART 1 - HEADQUARTERS

DEC 15 2003

This report is required by law (? USC 21 43) Failure to report according to the regulations can result in an order to cease and desist and to be subject lo penalties as provided for in Section 2150

Set reverse side for additionalintormation

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. ~~93-R-0435~~ 93V0006

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)

VA Greater LA Healthcare System
West LA Medical Center
11301 Wilshire Blvd
Los Angeles, CA 90073

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)

Buildings 113, 115, 117, 258, 304, 337

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 Anima 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 those 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		13	11		24
5. Cats					
6. Guinea Pigs	8		149		149
7. Hamsters					
8. Rabbits			52	32	84
9. Non-human Primates			1		1
10. Sheep					
11., Pigs					
12. Other Farm Animals					
13 Other Animals					
Rats	358	1801	2076	931	4808
Mice	698	678	3712	77	4467

ASSURANCE STATEMENTS

1) Professionallyacceptable 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 expfained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary **of all such exceptions is attached lo 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 veterinarianfor 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 CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/13/03

APHIS FORM 7023
(AUG 91)

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