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: 14-F-0009 CUSTOMER NUMBER: 463 FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT).

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, lesting, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Alached Listing

Α.	D N	C. Number of	D. Northwest 1	F	-
Anima's Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, lessing, experiments, research, or surgery but not ye used for such purposes.	animals upon which teaching, research, experiments, or tests were conducted	D. Number of animets upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pein or distress to the animels an for which appropriate anesthetic, anelgesic, or tranquilizing drugs were used.	E. Number of animats upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animats and for whithe 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 animats at the reasons such drugs were not used must be sittached this report.).	
4. Dogs					
5. Cats					
6. Guinea Pigs		Ţ			
7. Hamsters		37	492		529
6. Rabbita			2		2
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals	<u> </u>				
· · · · · · · · · · · · · · · · · · ·			1		
13. Other Animals		†			· ·
Mice	3,363	3,199	1,479	279	4,957
Rats	662	183	398		581
Ferrets	·	70	121		191

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestatic, analgesic, and tranquilizing drugs, prior to, during, and following actual restanching, testing, surgery, or experimentation were followed by this research facility.
- 2)- Each principal investigator has considered alternatives to painful 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 applicational 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 into brief explanation of the exceptions, as well as the species and number of animals effected.
- 4) The attending veterinerien for this research facility has expropriete authority to ensure the provision of adequate veterinery care and to oversee the adequacy of other aspects of entired care and use

	CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)	
SIG	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
	·	11-10-01

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

On



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

RO-17

Nutritional Immunology Laboratory

October 15, 2001

To:

Animal Care and Use Committee, HNRCA

From:

Re: Category E animals in Amendment to Protocol MS-31

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

SNW

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

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

To: Animal Care and Use Committee

From:

PI of WA-1 Protocol

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

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

We propose to conduct an in vivo intervention study to investigate the effectiveness of 9cis 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)-1butanone (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 protocol RO-17, "Roles of TNF and interleukin-1 in stress-induced cachexia: Effects of age in transgenic

mice"

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

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



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

November 10, 2003

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

Dear Dr. Goldentyer:

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

1) Animals reported under Category E:

- a) Mild non-infectious peritoneal inflammation was induced in sixty-one (61) mice by the intraperitoneal injection of thioglycollate to increase the total number of peritoneal macrophages available (which reduced the number of animals used) for peritoneal macrophage harvest. The letter of justification for category E research was submitted with the IACUC animal protocol and is attached.
- b) Lung tumors were induced in one hundred one (101) mice to examine the combined synergistic effects of vitamin A, vitamin D and COX-2 inhibitors to evaluate their role in lung cancer chemoprevention. The letter of justification for category E research was submitted with the IACUC animal protocol and is attached.
- c) Sarcopenia was induced in one hundred fifteen (115) mice by the subcutaneous injection of sterile turpentine into the hind limbs of the mice to evaluate if the cytokines involved in cachexia are the same as those of sarcopenia (namely TNF, IL-1 and IL-6) in an effort to understand and potentially alleviate the physiological or pathological processes leading to sarcopenia, wasting and cachexia. The letter of justification for category E research was submitted with the IACUC animal protocol and is attached.

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

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

"A" To R. Recension :=/09/04

This report is required by la result in an order to cease.	and desist and to be subj	to report according to ect to penalties as pro	the regulations of wided for in Section	on 2150 Cle	Set reverse side for additional information	018C BOA AN	HOM P30
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	ORT OF RESEA TYPE OR PRINT		Y .	USDA, 4101	ERS RESEARCH FACILITY (Name and Ad		red with USDA
3. REPORTING FACILITY (List sheets if necessary.)	all locations where anim	als were housed or us	sed in acrual reses	arch, lesting, L	eaching, or experimentations or held for the	ese purposes. A	tech additional
			CILITYLOCATION		INFAD	OR YOUR	
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REPORT OF ANMALS USED BY	OR UNDER CONTROL C	F RESEARCH FACIL	Y (Attach addition	ral sharts If ne	cersary or use APHIS FORM (023A)		· · - · · · · · · · · · · · · · · · · ·
A. Animats Covered By The Anima Wettere Regulations	B. Number of animals being bred, conditioned, or held for use in heaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of snimsts upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-reseving drugs.	D. Number of an which experit teaching, was suggety, or to conducted in accompanying distress to the and for which anesthetic, as tranquilizing a peed.	nimals-upon ments, sastin, ests were nothing grpein or e animals h appropriate halgesto, or	E. Number of animals upon which tead stportments, research, surperty, or test conducted involving accompanying p to the animals and for which the usoratestical analysesic, or transpullizing have solversely affected the procedure interpretation of the teaching, research experiments, surperly, or tests. (An experiments, surperly, or tests, (An experiments and the respons such drups animals and the respons such drups amust be attached to this report).	is were win or distress of appropriate drugs would is, results, or h, planation of trees in those	F. TOTALHO OF ANIMALS (Cols. C+ D+E)
4. Dogs							
5. Cats							
6. Guinea Pigs						<u>·</u>	
7. Hamsters					·		
8. Rabbits	24	<u>3</u> 4	0		0		34
9. Non-human Primates	<u>.</u>		·				
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 <u>·</u>		7
Deer Mice	18	24	0		0		24
and following actual research, 2) Each principal investigator has	leaching, testing, surgen	y, ar experimentation v O painful procedures.	vere followed by ti	his research fa			
principal investigator and appro addition to identifying the IACUC	wad by the institutional A ivapprovad exceptions, th	Animal Care and Use (his summary includes (Committee (IACU a brief explanation	C). A summa of the except	the associates and regulations be specified ny of all such exceptions in attached in lone, as well as the species and number of the veterinary care and to oversee the adec	this annual repo animals affected.	ertin .
	(Chief Exec		egally Respo	nsible ins	FACILITY OFFICIAL ditutional Official) Section 2143).		
I cartify that the above is true,			NAME & TITLE	OF CEO OR IN	NSTITUTIONAL OFFICIAL (Type or Print)	DAT	E SIGNED

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 YOU

Animals Covered By The Anima Welfare Regulations 12.&/CR 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 drups.	D. Number of animals upon which experiments, teaching, research, surgery, or lesses were conducted involving accompanying pain or distress to the animals and for which appropriate anesthafic, analysisic, or tranquitzing drups were used	E. Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animats and for which the use of appropriate anesthetic, analysis, or tranquilling 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 primets and the reasons such drugs were not used must be attached to this report).	TOTALNO OF ANIMAL (Cols. C D+E)
Fround Squirrels	0	30	0	. 0 .	30
ox <u>Squirrels</u>	0.	13	0	0	13
Skunks	0	33	. 0		33
Raccoons	0	67	0	0	67
Mountain Beaver	19	· 32	0	5	37
Stream Beaver	. 19	22	0	0	22
Thite Tail Deer	13 、	15	0	0	15
lack Tail Deer	90	57	0	0	57
oles	60	. 0	. 0	0	0
orcupine	. 3	- 0	0 ·	0	0
ocket Gophers	5	0 .	0	0	0
longoose	0 ·	. 6	. 0	0	6

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

(Chief Executive Office	ADQUARTERS RESEARCH FACILITY OFFICIAL or Legally Responsible Institutional Official) 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)	10/28/04

APHIS FORM 7023A

(AUG 91)

²⁾ Each principal investigator has considered atternatives to painful 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 attached.

⁴⁾ The stiending vaterinarian for this research facility has appropriate suthority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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 (QA-885) showed that chlorophacinone was the only underground bait that was 100% effective and readily consumed by mountain beaver. LiphaTech currently holds a chlorophacinone label in the form of paraffinized pellets. These pellets are delivered in bags to prevent weather damage. Another recent study (QA 1072) conducted in the Olympia Field Station habitat pens, showed that mountain beaver cached bags. Using LiphaTech's delivery system might reduce primary hazards as mountain beaver can cache baits inside their nests.

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

This is a preliminary study to determine if the LiphaTech product might be applicable to a field application. EPA regulations require that for final registration of a product that 70% efficacy with death as an end point be demonstrated. Since this data will support registration we therefore followed EPA regulations with a few modifications to account for a different species (

Standard rat anticoagulant place pack dry bait laboratory methods, Guideline #1.217).

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

COPY FOR YOUR INFORMATION

See reverse side for additional information.

Interagency Report Course No 0180-00A-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 82-V-001

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

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 (Siles)

531 VA Medical Center 500 West Fort Street

Boise, ID 83702

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 leaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, leaching, research, surgery, or lests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	Environments of the producing and the procedures producing and the procedures in the procedures and the procedures are the procedures. The producing accompanying pain or distress to the animals and lor 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).	TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			<u></u>		
9. Non-human Primates		·			<u> </u>
10. Sheep		₩ 26			\$ 26
11. Pigs					
12. Other Farm Animals					
13. Other Animals					<u> </u>
	 			 	

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including approxiate use of anesthetic, analysis, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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(Chief Executive Officer or	QUARTES RESEARCH FACILITY OFFICIAL Legally Responsible Institutional Official) iie, correct, and complete (7 USC Section 2143)	
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL		DATE SIGNED
		10/27/0

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

DEC 072004 See reverse side for

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.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

82-V-001

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

Department of Veterans Affairs VACO

additional information

810 Vermont Avenue NW Washington, DC 20420

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FACILITY LOCATIONS (Sites)

531 VA Medical Center 500 Vest Fort Street

Boise, ID 83702

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4. Dogs					
5. Cats					
6. Guinea Pigs			·		
7. Hamsters					
8. Rabbits	23	17	ë.	1	18
9. Non-human Primates					
10. Sheep	ļ		35		35
11. Pigs					
12. Other Farm Animals					
13. Other Animals					<u> </u>
Rats	12	18	78		96
Mice	7	22		76	98 \

- 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.
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CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official) 1 certify that the above is true, correct, and complete (7 USC Section 2143).			
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE DF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED	
		11/10/04	

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

Investigator:

Protocol #: OLS-0014B

Justification of Category E Animals

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

rabbits

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

See reverse side for

additional information. /2

interagency Report Covirol No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACIL (TYPE OR PRINT)

1. REGISTRATION NO. 82-V-001

1314 4/2 FORM APPROVED OMB NO. 0579-0036

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VACO

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531 VA Medical Center 500 West Fort Street

Boise, 10 03702

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 lests 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 leaching, 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	
5. Cats				INFORMATION	
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					
K Rots	12	13	73		9 5
Chice		22		76	98
•		I		,	

- 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

(Chief Executive Officer or I	UARTES RESEARCH FACILITY OFFICIAL Legally Responsible Institutional Official) e, correct, and complete (7 U.S.C. Section 2143)	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)

aust #1 1314 Regest #1 82-V-0001

Investigator:

Protocol #: OLS-0014B

Justification of Category E Animals

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

1 rabbits

COPY FOR YOUR

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.

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c Luuyee 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.

93-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)

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

Animals Covered By The Animal Welfare Regulations	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).	TOTAL NO. OF ANIMAL: (Cois. 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					
·					ļ
13. Other Animals					
Rats	62	688	927	552	2229
Mice	27	468	24	11	530

- 1) Professionally acceptable standards governing the care, freatment, and use of animals, including approxiate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL

(Chief Executive Officer I certify that the above it

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)

Explanation of Category E:

Rabbits

PI: Haake

Protocols: 0011-178

04044-02

Number of animals under Category E: 28

Procedures involving rabbits fall into Category E because of immunization with adjuvant, which is required for adequate B cell production. Rabbits are sedated with acepromazine 0.25-0.5 mg/kg SC or IM given 10-15 minutes prior to immunization.

PI: Ohning

Protocol: 01002-03

Number of animals under Category E: 4

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

Rats

PI: Mayer

Protocols: 99064-04 (VA project # 0041)

11091-02 (VA project # 0055)

Number of animals under Category E: 443

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

PI: Sattin/Pekary

Number of animals under Category E: 25

25 rats were categorized under Category E for the VA merit review study because the forced swim test is considered psychologically painful. These rats cannot be anesthetized because they would drown during the forced swim test.

PI: Tache

Protocol: 06069-02

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 # 06068-02, 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 #: 04044-02

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: 03030-02 (VA project # 0052) 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 # 0052). The end point of the chemical stimulation of the colon is significant pain

and discomfort that cannot be alleviated by analgesic since the aim of the study is to investigate pain behavior.

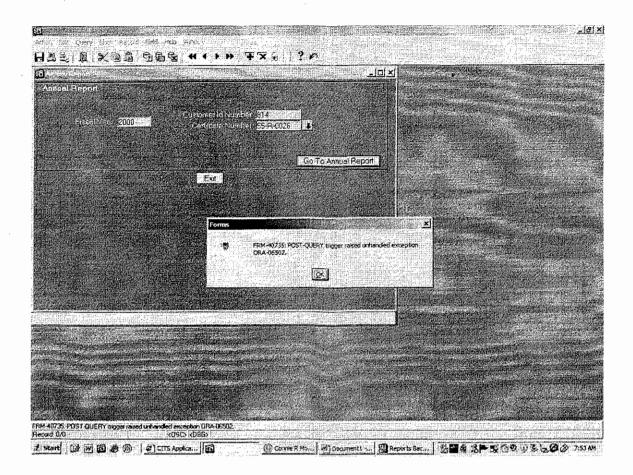
PI: Pandol

Protocols: 0111-42

01008-02

Number of animals under Category E: 40

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





Connie R Morris/CO/APHIS/USD A

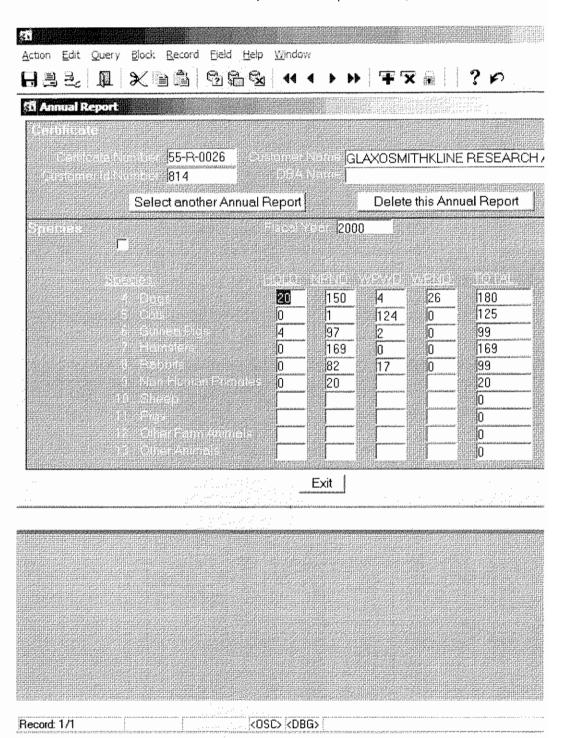
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To Teresa D Simpson/MD/APHIS/USDA@USDA

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Subject Annual report for 2000, 55-R-0026 ok?



T. REGISTRATION NO. 100 July 1

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ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

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2. HEADQUAIMERS RESEARCH FACILITY (Hamo and Address, as registered with USDA Michael Coder : ZV: CITOUM : ZV!

508 Fulton St. Durham, N.C. 27705

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REPORTING FACILITY (List all liscations where animals were housed or used in actual resignarily, leading, or experimentation, or held for these purposes.' Attach additional sheets in necessary.)

FACILITY LOCATIONS (Siles)

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Animals Covered By The Animal Wollaro Regulations	B Number of enimals 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-retieving drugs.	which exp teaching, teaching, curgery, o conducted accompan distress to and for will anesthelic	l animals upon eriments, research, research, resta wore Throuving lying pain or the animals inch appropriate is susjectic, or ng drugs were	experiments, res announced involve to the unimals at unexitation, analy have adversely a interpretation of resperiments, sur the procedures i	is upon which leaching, earth, surgery or lests were a lead of the work in a compunying pain or distress to which the use of appropriate pasie, or tranquilizing drups would allected the procedures; results, or the tenching, research, gery, or tests. IAn explanation of oreducing pain or distress in these masons such drups were not used to this report).	F. TOTAL NO. OF ANIMALS (Cois. C * O * E)
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. Cats			(12)	+ 31			43
Guinea Pigs				·			
. Hamsters					I		
. Rabbijs			(4) +	2			6
, Non-human Primates				reproductive and the commence of the commence	Agente-managers places are made of the second secon	(4)	4
0. Sheep					***************************************		
1 Pigs							
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- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including approxiate use of anesthetic, analysis, and tranquitizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by the research facility.
- 2). Each principal investigator has considered offernatives to painful procedures () indicates number reported in 2003 and
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that the standards and regulations be specified and explained by the principal investigator and approved by the institutional Animal Caro and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-upproved encaptions, this summary includes a brief explanation of the exceptions, as well as the species and number of unimals uffected.
- d). The attending vetermanan for this research facility has appropriate outborry to ensure the provision of adequate veterinary care and to oversee the adequacy of other appoints of principle care and use.

CERTIFICATION BY HEA	DQUARTES	RESEARCH	FACILITY	OFFICIAL
(Chief Executive Officer				

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

NAME LITTLE DE CEO DE INSTITUTIONAL DEFICIAL COM DESIGNA

DATE SIGNED

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SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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APHIS FORM 7023 (AUG 91)

ASSURANCE STATEMENTS

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

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER:

86-R-0031

FORM APPROVED OMB NO. 0579-0036

<11°

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

Sun Health Research Institute 10515 W. Sante Fe Dr. Sun City, AZ 85351

CUSTOMER NUMBER: 1698

Telephone: (623) -876-5328

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FACILITY LOCATIONS (Sites) - See Alached Listing

Animate Covered By The Animal Welfare Regulations	B. Number of entmat being bred, canditioned, or held for use in leaching, testing, experimenta, research, or surgery but not ye used for such purposas.	C. Number of enthmas upon which leaching, research, axperiments, or less were conducted involving no pain, distress, or use or pain-relieving.	D. Number of entimate upon which experiments, teaching, research, surgery, or teste were conducted involving accompanying pain or distress to the entimate an for which appropriate enesthetic, enalgestic, or trangulitzing drugs were	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying poin or distress to the animals and for which use of appropriate anesthetic, analysaic, or tranquitis drugs would have adversely affected the procedures, resort interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animats and the reast such drugs were not used must be ottached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
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! Dogs			_ '		0
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, Guinea Pigs					0.
/ Hamsters		_			0
. Rabbils	12	84	54	16	154
). Non-human Primates					0
0. Sheep			, and the same of		
1. Pigs	The second secon				0
2. Other Farm Animals					0:
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- 2) Each principal investigator has considered alternatives to painful 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 applicable investig

cital explanation	of the emophies of co of	()			
4) The ettending ve	eterinarian for this research fac	cilly has expropriate authority to ensu	re the provision of adequate veterinary care and to o	oversee the adequacy of other a	spects of animal care and use.
	,		DQUARTERS RESEARCH FACILITY OFFic r or Legally Responsible Institutional Official	1	
PHIS FORM 7023 (AUG 91)	(Replaces VS FORM	(OCT 88), which is obsolete.)	NAME & TITLE OF C.E.O. OR INSTITUTIONAL	OFFICIAL (Type or Print)	DATE SIGNED

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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

 HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, Include zip code)

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

Animals Covered By The Animal Welfare Regulations 12 &/OR 19 OTHER (List by Species)	B. Number of animals being bred, conditioned, or held for one in traching, terting, experiments, retearch 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 unimals upon which experiments, teaching, research, surgery or tests were conducted involving accompanying pain or distress to the arimable and for which appropriate anesthetic, analyzisk or tranquilizing drups were used.	E. Number of animals upon which teaching, experiments, research, aurgery or texts were conducted involving accompanying pain or distress to the animals and for which the case of appropriate anesthetic, aurgeste, or tranquilking drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery or tests. (as explanation of the procedures producing pain or distress in these animals and the crassons such drugs were not used until to attached to his report.)	F. TOTAL NO. OF ANIMALS (Coll. 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		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	00	85
Wild Mice	29	0	0	, 0	0
Llama	1 /	0	0	0	0
Chinchillas	0	0	29	0	29

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

(AUG 91)

4) The arending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other appears of animal care and use.

CERTIFICATION BY HE	EADQUARTERS RESEARCH FACILITY OFFICIAL	
	icer or Legally Responsible Institutional Official)	
I corrify that the at	bove in 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
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²⁾ Each principal investigator has considered alternatives to painful procedures.

³⁾ This facility is adhering to the translands and 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 Committees (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.

See reveren side for edditional information. Interspency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANNUAL AND PLANT HEALTH IMPPECTION SERVICE 1. REGISTRATION NO. A4-R-0040

1097

FORM APPROVED OND NO. 0579-0038

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

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 (870) 221-1090

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

FACILITY LOCATIONS (NEWS)

See Attached Listing 2625 Midpoint Dr. FT. Collins, CO 80525

2619 Midport Or . FT. Collins, CO 80525

2637 Midpoint D- FI Collins CO 80525

Animala Covered By The Animal Welfere Regulations	B. Rumber of animus being bood, conditioned, or held for use in teaching, feating, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or toots were conducted involving no pain, distress, or use of pain-refleving drugs.	(Affact) additional sheets if receal D. Number of animals upon which experiments, teaching, research, surgery, or feats were conducted involving accompanying pain or distress to the animals and for which appropriate anenthetic, analgesto, or tranguilizing drugs were used.	E. Number of entimals upon which teaching, experiments, research, surgery or teats were conducted impolying accompanying pain or distress to the animals and for which the use of appropriate ensembletic, an alternational trave adversely affected the procedures, results, or interpretation of the leaching, research, experiments, surgery, or tests. (An experiment and the procedured producing pain or distress in these submets and the response 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
8. Gulnes Pigs	0	0	0	. 0	0
7. Hamsters	0	116	0	0	116
8. Rabbita	0	108	6	0	114
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Piga	0	0	3		3
12. Other Farm Animals	. 0	0	0	0	0
13. Other Animals		0	0	0	0
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- Professionally ecceptable standards governing the care, trastment, and use of snimals, including appropriate use of sneathedic, analgedic, and tranquitions drugs, prior to, during, and following scrust represents, leading, teating, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
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- 4) The attending voterinarian for this research facility has appropriate authority to ensure the provision of adequate valuativery care and to oversee the adequacy of other espects of entired care and use.

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CERTIFICATION BY	HEADQUARTERS RESEARCH FACILITY OFFICIAL	
(Chief Executive C	Officer or Legally Responsible institutional official)	
I certify that the at	cove is true, connect, 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
•		10-29-63
- CF		

APHIS (AU (Replaces VS

18-23 (Out 88), which is obsolete

PART 1 - HEADQUARTERS



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.

Degragency Report Control No DIRCLOGAN This reports required by law (7 USC 21/3) Failure to report absorping to the regulations can result in an artist to sease and desist and to be subject to penalties as provided for in Section 21/50 PORM APPROVED ONE NO. 0479-0036 Annyal and plant hen incut of agreculture. . MECRETRATION MO 14-R-0048 2. HEADQUIANTERS REGISARCH FACELTY (Name and Address, se registered with USDA brokeds ZID Code) Southwest Texas Skale University CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY 601 University Drive (TYPE OR PRINT)

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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.

See attached form for negarmelal lanestible Interagency Report Control No.: 0180-DOA-AN

FORM APPROVED OMB NO. 0578-0038

CUSTOMER NUMBER: 1461

1. CERTIFICATE NUMBER: 43-R-004B

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

University of Missouri, Columbia, MO 6521!

University Of Missouri-Columbia 205 Jesse Hall

Telephone: (573)882-9500

Columbia, MO 65211

2. REPORTING FACILITY (List all locations where animals were housed or used in schial research, bening, or experimentation, or neid for these purposes. Attach additional element if necessary)

FACILITY LOCATIONS (Sties) . See Absolved Liming

Anisteis Covered By The Animal Weifare Regulations	B. Number of shims being bred, ceedstoned, or half for use in touching, excelling, experiments, research, or surgery but not yet used for each purposees.	C) Number of animals upon which teamling, research, experiments, or least were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which appelments, beaching, frasearch; surgesty or today work conducted involving pear or distress to the animals and for which superportate areachatic, a paligosic, of transpulsing drugs wore used.	E. Number of snimate upon which teaching, experiments, research, surjerry or tests were conducted involving scompanying: pain or distress to the animate and for which the use of appropriate ensembled, analysels, or transplating drugs would have animate pricedures, creatile, or interpretation of the traching, research, experiments, aurgory, or bette. (An explanation of the procedures producing pain or distress. In these animats and the procedures producing pain or distress. In these animats and the transport such drugs were not used must be attached to this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
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"'amsterne	0	192	0	0	192
-cabbla	15	39	164	0	203
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). Sheep	2	50	158	. 0	208
		799	24	39	862
. Pigs	529		48	0	492
Catcle		Lelady	15	9	73
horses	10	49	. 15		
3. Other Animula					215
bats	8	190	25	0	5
opossum	0_	0	5	0	150
wild mice	0	150	0	D	130

- Processionally ecceptable etandards governing the care, treatment, and use of animals, including appropriate use of anadasic, analysis, and research reciting, bearing, surgery, or experimentation was followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and requisitions under the Act, and it has required that exceptions to the standards and requisitions be specified and explained by the principal investigator and approved by the institutional Animal Care and Use Committee (ACUC). A summery of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this elements includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending verminarium for this research facility has appropriate authority to ordere the provision of adequate verminary care and to oversize the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer of Legally Responsible Institutional Official) Carilly that the score is true, correct, and complete. (7 U.S.C. Section 2143)

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

DATE: SIGNED 11/20/00

See reverse side to additional intermation. Interagency Report Control No. 0180-00A-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)

Z HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA University of Missouri-Columbia 205 Jesse Hall Columbia, MO 65211

of activities are by A	A UNDER CONTROL OF	RESEARCH FACILITY	(Artach adiditional sheets if pec	essary or use this form.	
Animals Covered By The Animal Wallare Regulations 12, &/OR 13. Other (Ust 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 work conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analyssic, or trangullizing drugs were used.	E. Number of animals upon which leaching, 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 (COIS. C = D + E)
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- 1). Professionally acceptable standards governing the care, treatment, and use of animals, including apprortate use of anesthetic, analyssic, and tranquilizing drugs, prior to, during, and following actual research, leaching, testing; surgery, or experimentation were followed by this research facility.
- .2). Each principal investigator has considered alternatives to painful 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 velorinarian for this research facility 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).

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

DATE SIGHE:

11/20/00

University of Missouri-Columbia (43-R-048)

Annual Report of Research Facility - Attachments

\CILITY LOCATIONS:

Allton Bldg.

-lab: room 233, 234

Animal Science Research Center

-animal housing facility: ASRC Units 8, C, D, F,

-labs: E142, N126, N152, N153, & N190

Civdesdale 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, 1112, 114, 116, 118, 124, 221A, 225A, 226, 228, 230, 233A, 233B, 311, 312, 313, 329,

331, 334

Habs: 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

ddlebush Farm

-animal housing and use: Equine Center, Therlogenology Bldg., paddocks

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ANNUAL REPOR				Dept of Veterals Affairs Research + Development Computing Center 103 South Gay Street-412 Floor, Room 400 Baltimore MD 21202-4051			
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6. Guinea Pigs							
7 Yamsters		I		1		Į.	
3. Aabbits		41					41
. Non-human Primales						ţ	
10. Sheep					Correction:		
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2. Other Farm Animals			ATTOCATE STATE OF THE STATE OF		auted 30	JAIL DA	Sent to the sent t
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principal investigator and app	woved by the institution	riol Animal Care and L	isa Commili	60 (TACUC). A BUT	na ic the Benderos and regulations is simary of pil such exceptions is alt exceptions, as well as the species and	ached to this annua	I report. in
4). The altending velorinarial for primal care and use.	this research lacility h	es appropriate nuthor	ity so ensur	the provision of s	dequate veterinary core and to overse	at the adequacy of sti	ner bepacis of
	CERTYEACA	TION BY HEAT	QUART	ns resea ho	H FACILITY OFFICIAL		
	(Chief Ex		r Legally	Responsible.	Institutional Official)		
TURE OF C.E.O. OR INSTITUTE					OR INSTITUTIONAL OFFICIAL (Type	u Pinti	DATE SIGNED
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PHIS FORM 7023 (AUG 91)

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

8 2004 JUL

See reverse side for additional information. Interugency Report Control I 0180-DOA-AN

united states department of Agriculture ANIMAL AND PLANT HEALTH INSPECTION SERVICE REGISTRATION NO. 93-7-004

FORM APPROVED OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as royistered 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 sheats if nocessary.)

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 addictional sharle it independent or 1000 APHIS FORM 7023A.)							
A. Animals Covered By The Animal Wellere Regulations	B. Number of animals boling bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used to such purposes.	C Number of animals upon which teaching, research, experiments, or lests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of articular upon which superiments, teaching, research, surgery. In feets were conducted involving accompanying pain or distress to the antimute and for which appropriate anesthetic, analysisk, or tranquitizing druck were used.	E Number of animals upon which leaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgeate, or tranquitizing drugs would have adversely affected the procedures, results, or interpretation of the tapching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distors in these animals and the reasons such drugs were not used through be attached to this tapus).	F. TOTAL NO. OF ANIMALS (Cots. C + D + E)		
4. Dogs					0		
5. Cats					0		
6. Guinea Pigs	0	0	101	O	101		
7. Hamsters					0		
9. Rabbits	0	3	91	1527	1621		
9. Non-human Primates					0		
10. Sheep					0		
11. Pigs	:				0		
12. Other Farm Animals		4.4		·	0		
13. Other Animals		,					
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A SECOND CONTROL OF THE PROPERTY OF THE PROPER	!						
ASSURANCE STATEMENTS							

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including approximate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during. and following actual research, teaching, testing, surgery, or experimentation were todosed by this research facility.
- 2). Each principal investigator has considered afternatives to paintiff procedures.
- 3). This tacility is adhering to the standards and 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 Core and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-upproved exceptions, this summary includes a brief application of the exceptions, as well as the species and number of animals affected.
- The attending valorinarian for this research facility has appropriate bufforty to ensure the provision of adequate valorinary care and to oversee the adequacy of other especies of boimal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
Office by active to the second of the second
(Chief Executive Officer or Legally Responsible Institutional Official)

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

DATE SIGNED

SIGNATU

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

APHIS FORM (AUG 91)

See revette side for additional information. Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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SUGAR LAND, TX 77478

1. REGISTRATION NO.

include Zio Codel

CUSTOMER NO.

FORM APPROVED DMB NO. 0578-0038

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

74-R-0049 1503

2. HEADQUARTERS RESEARCH FACILITY (Namo and Address, its registered with USDA,

STILL MEADOW INC. 12852 PARK ONE DR SUGAR LAND, TX 77478

REPORTING FACILITY (List oil locations where entimate were housed or used in actual research sheets if necessary.)	h, teating, teaching, or experimentation, or haid for those purposes. Attach additional
PACILITY LOC	ATKINS(stor)
SITE1	

REPORT OF AMMALS USED BY DR UNDER CONTROL OF RESEARCH FACILITY (Assert additional abselts if recessary or use APHIS FORM 7020A) B. Niember of O. Number of enimals upon C. Number of E. Number of animals upon which leaching, animala beino Rody slamins which someriments, experiments, restaursh, surgery or basts were Animals Coursed bred, which leaching. teaching, research, conducted involving accompanying pain or distress TOTAL NO. By The Animal conditioned, or research, surpory, or texts were to the animals and for which the use of appropriate Walters Regulations OF ANIMALS held for use in experiments, or conducted involving anesthetic eneignaic, or tranquilizing drugs would teaching, teating. LOSSIA beresta accompanying pain or have adversely affected the procedures, results, or (Cals. C + യോട്ടേന്നുവേർ അടങ്ങോടി, വ COLUMNISH interpretation of the beaching, research, distress to the animals 0-6 involving no and for which appropriate experiments, surgery, or tests. (An explanation of the procedures producing pain or districts in trium surgery but not DRAIL CUSTOMS, OF enembers, energetic, or yet used for such use of painmanquilizing drugs were anknote and the reasons such drugs were not used reliaving drugg must be attached to this report) 4. Dogs 158 531 8 24 563 5. Cats 49 155 24 179 6. Guinea Pigs 541 29 570 7. Hamsters AA 20 108 8. Rabbits 1200 140 1340 9. Non-Human Primates 10. Sheep 11. Plgs 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 anestholic, analysis, and tranquillizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered atternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and il 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 Lisa Committee (IACUC), A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-suproved exceptions, this summary includes a brist application of the exceptions, as well as the species and number of animals effected.
- 6) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of artimal care and use.

CONTRACTOR OF THE PROPERTY OF	The state of the s		
	(Chief Executive	Y HEADQUARTERS RESEARCH FACILITY OFFICIAL. Officer or Legally Responsible Institutional official)	
	i certify that the a	bove is true, correct, and complete (7 U.S.C. Section 2143)	•
SIGNATURE OF C.E.O. O	OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		N. C.	11/21/2003
APHIS FORM 7023	(Replaces V3 FORM 18-23 (Oct 88), wi	Not is observe PAI	RT 1 - HEADQUARTERS

74R0048

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.

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 imitation (usually redness or swelling) that may have been caused by the test material. We do not always use anesthetics because we may not be able to distinguish between discoloration caused by the test material and discoloration possibly caused by an anesthetic.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: USEPA Health Effects Test Guidelines, Office of CFR: Prevention, Pesticides and Toxic Substances, OPPTS 870-1200, Acute Dermai Toxicity, OPPTS 870-2400, Acute Eye Imitation, OPPTS 870-2500, Acute Dermai Imitation, OPPTS 870-2600, Guinea Pig Sensitization

Approval Status: Approved/Disapproved By: Date:

Disapproved Reason:

his report is required by law (7 USC 2143). Fallure to report according to the regulations can Built in air order to cause and desist and to be subject to penalties as provided for in Section 21

> 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 HIII Road Kenilworth, NJ 07033

Telephone: (908) -298-4000

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

FACILITY LOCATIONS (Sites) - See Alacted Using

Animala Covered By The Animal Waifare Regulations	B. Number of - animals being bred, conditioned, or held for use in leaching, 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 or pain-relieving drugs.	D. Number of animals upon which experiments, (eaching, research, surgery, or lests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgests, 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 whither use of appropriate aneathetic, analgestic, or tranquilized trugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, aurgary, or tests. (An explanation of the procedures producing pain or distress in these animals a than reasons such drugs were not used must be attached this report.).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C+D+E)
Dogs	0	94	151	3	248
Cats	0	0	27	0	27
Guines Piga	0	4381	2435	0	6816
Hamsters	0	0	110	0	110
Rabbits	0	615	352	11	978
Non-human Primates	95	470	413	8	891
Sheep	0	0	0	0	0
Plga	0	0	0	0	0
Other Farm Animals	0 .	O	0	0	0
Other Animals					
Gerbils	0	48	4272	0	4320

SSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of entirets, including appropriate use of enteretic, analgesic, and tranquilizing drugs, prior to, during, and following actual research feeting, treating, surgery, or experimentation were followed by this research feetility.
- 2) Each principal invastinator has considered atternatives to painful procedures.
- 3) This facility is adhering to the standarde and 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 Core and Use Committee (IACUC). A summary of all such exceptions is attached to this senual report. In addition to identifying the IACUC-approved exceptions, this summary int. brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending vectorinarian for this research fecility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

(Chief Everythia Officer or Length Deanangible Inglithitians	al Michal \
CERTIFICATION BY HEADQUARTERS RESEARCH FACIL	MY OFFICIAL
	CONTROL OF THE PROPERTY OF THE

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

DATE SIGNED

(1/25/0

Customer ID and Site Address: Site | 1

ID: 181

2000 Galloping Hill Rd Kenliworth, 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

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-009

PORM APPROVE DMB NO. 0579-0038

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, 66 registered with USDA Include Zip Code)

Department of Veterans Affairs Central Office 810 Vermont Avenue, NW Washington, DC 20420

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

FACILITY LOCATIONS (SII'ds)

South Texas Veterans Health Care System Audie L. Murphy Division

7400 Merton Minter Blvd.

TY 78284

Annual control of the	/8284	sia (1000) kana ana ana ana ana ana ana ana ana an		and the state of t		······································
REPORT OF ANIMALS USED BY O	A UNDER CONTROL OF	RESEARCH FACILITY	(Attach schifflingal sheets if no	במנים אר עדם AF	HIS FORM 7023A)	
Animals Covered By The Animal Weltare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not lyel used for such purposes.	C Number of unimple upon which (eaching, research, experiments, or tests were conducted hivolving no pain, distress, or use of pain-relieving drugs.	D. Number of annihals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which apprepriate anisthatic, analysists, or tranquitising drugs were used.	experiments conducted to the enimit anesthette, t have advers interpretatio experiments the procedu animals and	initiobs upon which toaching, I research, surgery or tests were research, surgery or tests were plant or distress its and for which the use of appropriate analysis, or tranquilizing drugs would ely allested the procedures, results, or in of the teaching, research, is surgery, or tests. (An explanation of the producing pain or distress in these the reasons such drugs were not used acched to this report).	F. TOTAL NO. OF ANIMALS (Cols. C * D + E)
4. Dogs	'		Same in the second seco		A APPLICATION OF THE STREET, AND ADDRESS OF THE STREET, AND ADDRESS OF THE STREET, ADDRESS	
5. Cals			y and the second			
6. Guinea Pigs	<u> </u>			- A. COO ON THE PROPERTY AND THE PROPERT	,	
7. Hamsiers			15		60	75
8. Rabbits	MANA		41			41
9. Non-human Primates	anno espinatora processo e e e e e e e e e e e e e e e e e e		- Committee and Angley Science Committee Conference Angles Conference Committee Conference Committee Conference Committee Conference Committee Conference)	
10. Sheep	Microphysical Commission Commissi	A A Server Section Sec	CONTROL OF THE PROPERTY OF THE			r
11. Pigs			A ACCORDANGE OF THE PROPERTY O			
12. Other Farm Animals		- ANDREES - ANDRES	as an annual construction of the second of t		Accessors to the second	
13. Other Animals						
Rats	Allen And Allen	198	36		397	631
Mice	8523	4604	4342	The second control of the second seco	9076	18022
ASSURANCE STATEMENTS						

- 1). Protessionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analysis, and tranquilizing drugs, prior to, during, and following actual research, Isaching, Issting; surgery, or experimentation were followed by this research facility.
- 2). Each principal investigator has considered alternatives to painful procedures.
- 5). This locility is adhering to the standards and 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 ottending velorinarian for this research facility 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).

Type or Print

DATE SIGNED

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

(TYPE OR PRINT)

1. REGISTRATION NO.

FORM APPROVED BC00-8520 OM BMC

ANNUAL REPORT OF RESEARCH FACILITY

2. HEADQUARTERS include Zip Code)

14-R-0009, Cust ld 105

CISCA (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 II necessary.)

FACILITY LOCATIONS (Siles)

Boston University Medical Center Lab Animal Science Center, 700 Albany Street

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Affect Buildings) should if ngcessury of use APHIS FORM 7023A)							
A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being head, conditioned, or held for use in leaching, testing, experiments, research, or surgery but not it 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.	O. Number at animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate antalhelic, 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, analgeste, or tranquitizing 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. Gulnea Pigs	Ø	108	Ø	Ø	108		
7. Hamsters	8	Ø	Ø	Ø	Ø		
sabbita	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	ф.	498		
13. Other Animals Ferrets	Ø	Ø	La constante de	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, freatment, and use of animals, including apprortate use of anesthetic, analgesic, and tranquitizing drugs, prior to, during, and following actual research, reaching, testing, surgery, or experimentation were followed by this research facility.
- 2). Each principal investigator has considered alternatives to painful procedures.
- 3). This inclidy is adhering to the standards and 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 attached.
- 4) The attending veterinarian for this research legility has appropriate authority to ensure the provision of adequate veterinary date and to oversee the adequacy of other especies of animal care and rise.

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

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

DATE SIGNED

ATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

APHIS FORM 7023 (AUG 91)

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

See reverse side for Additional intomation Intersigency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
- ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

55-R-0026, Cust ld 814 2 MEADQUART

include Zip C ... GLAXO WELLCOME INC.

FIVE MOORE DR. RESEARCH TRIANGLE PA, NC 27709

3. REPORTING FACILITY (LIST all locations where animals were housed or used in scient research, testing, teaching, or experimentation, or held for these purposes. Attach additional Sheets II INCOTERV.)

A", ". "

FACILITY LOCATIONS (5Hea)

Drug Evaluation Lab, Moore Drive Site:

Cornwallis Road Site:

Toxicology Animal

Drug Safety Assessment

Facility, Research Commons II

Animate Covered By The Animal Wellare Regulations	E. Number of primals being bried, conditioned, or test for use is teaching, texting, experiment, or surgery but not yet used for sech purposes.	C Number of antifulic upon which leaching, research, experiments, or leafs were conducted involving so pain, distress, or use of pain-relieving drugs.	D. Number of semnals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pale or distings to the animals and for which appropriate anesthetic, unalgratic, or trangulizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or texts were conducted involving potompanying path or distress to the animals and for which the use of appropriate anesthetic, anelgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, suggery, or texts. (An explanation of the procedures producing path or distress to these animals and the reasons such drugs were not used must be affected to this report).	TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	20	150	4	26	180
5. Cata	0	1	124	0	125
6. Guinea Pigs	4	97	2	0	99
7. Hemsters	0	169	0	0	169
8. Rabbit	0	82	17	0	99
9. Non-human Primates	0	20	0	0	20
0. Sheep	, N/A	0	0	0	0
11- Plas	N/A	0	. 0	0	0
12. Other Farm Animals	N/A	0	0 :	0	0
13. Other Animals	N/A	Ô	0	0	0

- 1) Protessionally acceptable standards governing the care, teatment, and use of animals, including approviate use of anesthetic, analysis, and tranquiliting drugs, prior to, during, and tollowing actual receirch, teaching, teating, surgery, or experimentation were followed by this research facility.
- 2). Each principal investigator has considered alternatives to pointul procedures.
- 2). This locitity is adhering to the standards and 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 the Committee (IACUC). A summery of all such exceptions is attached to this annual report. In adultion to identifying the IACUC approved exceptions, this summery includes a birel explanation of its exceptions, at well as the species and number of animals effected.
- 4). The attending vetermannum for this research tatality has appropriate authority to ensure the provision of adequate veterinary cars and to average the adequacy of other aspects of unimal care and use.

CENTIFICATION 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				
		BONOUZE				

APHIS FORM 7028 (AUG 91)

(Augigulia VS FCIAM 18-23 (OCT 88) which is obscibile)

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

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

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