

NOV 18 2002

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 35-R-0030 CUSTOMER NUMBER: 640	FORM APPROVED OMB NO. 0579-0036 <i>CM</i>
Covance Laboratories, Inc. 3301 Kinsman Boulevard Madison, WI 53704 Telephone: (608)-242-2712		

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

FACILITY LOCATIONS (Sites) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		1382	419	∅	1801
5. Cats		7	∅	∅	7
6. Guinea Pigs	82	271	∅	488	759
7. Hamsters		480	∅	∅	480
8. Rabbits	58	981	1220	38	2239
9. Non-human Primate	231	1340	288	∅	1628
10. Sheep					
11. Pigs		40	106	∅	146
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)			
SIGNATURE	OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print	DATE SIGNED
			11/8/02

ED 11/21/02

35 R 30

ATTACHMENT 1

Facility Sites Listing

35-R-0030

Site: 001 Covance Laboratories Inc. Contact:
Status: Active 3301 Kinsman Boulevard
 Madison, WI 53704
 County: Dane

Site: 002 ASL
Status: Deleted Building 3
 3802 Packers Ave.
 Madison, WI 53704
 County: Dane

Site: 003 Oak Grove Farm
Status: Deleted 5919 Oncken Road
 Waunakee, WI 53549
 County: Dane

Site: 004 Sunrise Farm
Status: Deleted AEF Building
 6315 Kopp Road
 Waunakee, WI 53549
 County: Dane

ATTACHMENT 2
Page 1 of 1Attachment to USDA Annual Report 2002
Explanation regarding animals listed in category E

Rabbits:	18	Skin Irritation/Toxicity Studies
	<u>20</u>	Ocular Irritation Studies
	38	Rabbits in category E
Guinea Pigs	488	Dermal Sensitization and Maximization Studies
	<u>488</u>	Total guinea pigs in category E

Category E includes 18 rabbits involved in skin irritation or toxicity studies. Animals identified as having pain are those that developed focal skin necrosis resulting from administration of test material. Treatment of the skin lesion with anesthetics would potentially interfere with the observations and the endpoint of the study. Any animals that exhibited behavioral signs of discomfort were removed from the study and humanely euthanatized.

Twenty (20) rabbits in category E were used on eye irritation studies. Rabbits on eye irritation studies are routinely administered predose topical anesthetics when prescreening of the test material suggests a potential for ocular irritation. These 20 animals represent instances where unexpected irritation was noted as judged by the animal pawing at the treated eye and/or vocalizing. Treatment of the eye with analgesics following test material administration would potentially interfere with the observations and the endpoint of the study. Any animals exhibiting extreme ocular damage or more than momentary discomfort were removed from the study and humanely euthanatized.

Category E includes 488 guinea pigs involved in Dermal Sensitization and Maximization studies. Animals identified as having pain are those that developed focal areas of skin necrosis resulting from administration of test material or injections of Freund's Complete Adjuvant. Treatment of skin lesions with anesthetics would potentially interfere with the observations and the endpoint of the study.

All of the above listed animals in category E were used on studies going to regulatory agencies regarding product safety or toxicity testing. These tests are required of our clients by state, federal, or regulatory agencies. During the conduct of these studies it was imperative that the animals receive no drugs that might interfere with the testing in order to assure study validity. These activities and procedures of conduct for the studies were reviewed and approved by the Institutional Animal Care and Use Committee.

The regulations that may require these procedures included 21 CFR 58 (FDA), 40 CFR 160 (EPA-FIFRA), 40 CFR 792 (EPA-TSCA), ENV/MC/CHEM(98) 17, Revised 1997, Issued 1998 (OECD), 59 NohSan No. 3850 (Japanese MAFF), and Ordinance 21 (Japanese MOHW).

35-R-0030

ATTACHMENT 3

SUMMARY OF EXCEPTIONS

There were no exceptions to the standards in 2002.

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)

2. HEI/ inc. 21-R-0168. Cust Id 402

S T S DUOTEK, INC.
7500 W. HENRIETTA ROAD
RUSH, NY 14543

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)

7500 W. Henrietta Rd Rush NY 14543

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		496		293	3427
7. Hamsters					
8. Rabbits		258	218		476
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11-30-00

A (AUG 97)

(OCT 88), which is obsolete)

KAC

PART 1 - HEADQUARTERS



**STERILIZATION
TECHNICAL
SERVICES**

division of STS duoTEK, Inc.

7500 West Henrietta Rd. • Rush, New York 14543 • Tel: 716-533-1672 • Fax: 716-533-1796

Annual Report Addendum, 2000, Facility No. 21-R-168
Category E Explanation

The Guinea Pig (b)(4) Test is a procedure which determines the allergenicity of materials. This study is required by the FDA Modified ISO 10993-1 matrix for preclinical evaluations of Class II and III medical devices. In this procedure, an adjuvant and saline extract are injected intradermally. The adjuvant enhances the immune response and does result in lesion formation at the injection site. These lesions, ranging in size from (b)(4) (b)(4) are not treated due to the possible interference or enhancement of the sensitization response. In order to determine the health status of these animals, daily observations are performed and animal health technical personnel evaluate the sites. Any abnormal findings are reported to the Attending Veterinarian for assessment. During this period, 10/01/99 to 9/30/00, none of the 2931 guinea pigs used in this evaluation required additional veterinary care for problems related to the lesions.

In order to address pain and distress, the Attending Veterinarian researched analgesics and an appropriate oral medication which would not affect the animals' fluid intake was not available. The nature of the Guinea Pig (b)(4) Test negates the use of topical analgesia. We also performed weight trends and the animals exhibited weight gain throughout the test procedure. The animals ambulated normally and only vocalized when handled (as is the case with untreated guinea pigs).

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UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 21-R-0168	CUSTOMER NO. 402	FORM APPROVED OMB NO 0579-0036
2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)		
S T S DUOTEK, INC. 7500 W. HENRIETTA ROAD RUSH, NY 14543 (716) 533-1672		

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)
12-03-2001 RCV

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(sides)

See Attached Listing

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4. Dogs					
5. Cats					
6. Guinea Pigs	90	338		2066	2404
7. Hamsters					
8. Rabbits		134	239		373
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

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

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

DATE SIGNED

11/30/01

HEADQUARTERS

Signature

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 21-R-0168
Customer Number: 402
Facility: S T S DUOTEK, INC.
7500 W. HENRIETTA ROAD
RUSH, NY 14543
(716) 533-1672

STERILIZATION TECH SERVICES
7500 W. HENRIETTA RD
RUSH, NY 14543



**STERILIZATION
TECHNICAL
SERVICES**

division of STS duoTEK, Inc.

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In order to address pain and distress, the Attending Veterinarian researched analgesics and an appropriate oral medication which would not affect the animals' fluid intake was not available. The nature of the Guinea Pig (b)(4) Test negates the use of topical analgesia. We also performed weight trends and the animals exhibited weight gain throughout the test procedure. The animals ambulated normally and only vocalized when handled (as is the case with untreated guinea pigs).