This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21! NOV 26 2003 See attached form for additional information. Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 50-R-0001
CUSTOMER NUMBER: 41

FORM APPROVED
OMB NO. 0579-0036

E. I. Dupont Denemours & Company, Inc.
Haskell Laboratory
Elkton Road
P.O. Box 50
Newark, DE 19714

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

FACILITY LOCATIONS (Sites) - See Atached Listing Site #001, Haskell Laboratory, Bldg 1

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits	2	314	0	49	363
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					
13. Other Animals					0

ASSURANCE STATEMENTS

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

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

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

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

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

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

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

DuPont Haskell Laboratory
for Health and Environmental Sciences
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

November 24, 2003

Elizabeth Goldentyer, DVM
USDA, APHIS, REAC
Eastern Regional Office
920 Main Campus Drive
Raleigh, NC 27606

Dear Dr. Goldentyer:

To address the issue of the category E animals in the USDA annual report of the DuPont Haskell Laboratory for Health and Environmental Sciences (50-R-0001), I am providing a list of two types of skin irritation studies, three types of eye irritation studies and four copper toxicity studies, which were conducted in rabbits to meet the criteria of various regulatory agencies or for safety assessment. All study protocols and SOP's were reviewed and approved by the Haskell Laboratory's Institutional Animal Care and Use Committee (IACUC).

Skin Irritation Studies

Eleven (11) rabbits that were used in one of the following tests experienced signs that were considered to fall into category E. These studies comply with or are based on (screening studies) test guidelines OPPTS 870.2500 (1998) and OECD 404 (1992).

1. Skin Irritation Study in Rabbits – The purpose of this study is to supply safety assessment information and to enable companies to file for pre-market notifications (PMNs).
2. Acute Dermal Irritation/Corrosion Study – This study is conducted for the registration of products with the Organization for Economic Cooperation and Development (OECD) and/or the Environmental Protection Agency (EPA).

Eye Irritation Studies

Four (4) rabbits that were used in one of the following tests experienced signs that were considered to fall into category E. These studies comply with or are based on (screening studies) test guidelines OPPTS 870.2400 (1998) and OECD 405 (1987).

1. Eye Irritation Study – The purpose of this study is to supply safety assessment information and to enable companies to file for pre-market notifications (PMNs).

2. Acute Eye Irritation/Corrosion Study – This study is conducted for the registration of products with the Organization for Economic Cooperation and Development (OECD) and/or the Environmental Protection Agency (EPA).

3. Eye Irritation Screen – The purpose of this study is to supply safety assessment information for Discovery compounds.

Testing for registration of crop protection chemicals is required under CFR 40 Part 158. Other testing is done for product stewardship purposes, for the reasons cited above.

The IACUC approved the conduct of these studies without the use of anesthetics, analgesics or tranquilizing drugs because the use of such drugs could adversely influence the experimental compound's effect on the animal or alter the animal's reaction to the experimental compound, resulting in invalid interpretation of the clinical signs by the scientists. Test guidelines (OPPTS) for these study types do not allow for the use of anesthetics, analgesics, or tranquilizing drugs, other than allowing use of local anesthetics in eye irritation studies where extreme pain is expected. Most tested substances are novel materials for which there is little or no information available upon which to predict the response. Test substances are not tested if it is expected they will produce corrosion or severe irritation (e.g., based on pH). The materials for registration studies are tested in step-wise fashion (one rabbit first, then two more if the first does not display severe response) if the test substance may be expected to produce a severe response, based on data from similar materials.

Copper Toxicity Studies

Thirty-four (34) rabbits were used in one of the following tests experienced signs that were considered to fall into category E. The 24-day tolerability study was designed to select dose levels for a subsequent pilot developmental toxicity study. The 28-day tolerability study tested the toxicity of five copper substances in preparation for the pilot study. The pilot study set the dose level for the main study. The main study complies with test guidelines U.S. EPA Health effects Guidelines OPPTS 870.3700. Prenatal Developmental Toxicity Study (August, 1998); International Conference on Harmonization (ICH). Tripartite Guidelines on Detection of Toxicity to Reproduction for Medicinal Products, Federal Register, September 22, 1994, Section 4.1.3.

1. A 24-Day Tolerability. The purpose of this study was to determine the tolerability of a copper substance administered orally by gavage to non-pregnant rabbits for 23 consecutive days.

2. A 28-Day Tolerability. The purpose of this study was to determine the maximum tolerated dose for five copper test substances.

3. Pilot Developmental Toxicity. The purpose of this study is to provide preliminary assessment of maternal and developmental toxicity of the test substance.

4. Developmental Toxicity. The purpose of this study is to evaluate the developmental toxicity of a test compounds administered to assumed pregnant rabbits during gestation.

The IACUC approved the conduct of these studies without the use of anesthetics, analgesics or tranquilizing drugs because the use of such drugs could adversely influence the experimental compound's effect on the animal or alter the animal's reaction to the experimental compound, resulting in invalid interpretation of the clinical signs by the scientists. Test guidelines (OPPTS) for this study type do not allow for the use of anesthetics, analgesics, or tranquilizing drugs.

DuPont actively supports research programs to develop scientifically acceptable refinements and alternatives to animal testing. We do use a commercially available in vitro system (Corrositex®) as a screen. We have also developed and validated the mouse local lymph node assay, which is used as a replacement for guinea pig dermal sensitization. This assay is a refinement of the sensitization testing which involves much shorter exposures, and uses fewer animals, than the guinea pig assays. In those cases where an in vitro system provides sufficient information, no additional studies with animals are performed. At present, there are no validated alternatives that would completely replace animal tests which are required by national and international laws and regulations.

Also, please note that there were no exemptions or exceptions to any USDA regulations and standards to report for this year.

Sincerely,

(b)(6), (b)(7)(C)

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 50-R-0003
CUSTOMER NUMBER: 27

FORM APPROVED
OMB NO. 0579-0036

Intervet, Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966

Telephone: (302) -934-8051

NOV 1 2003

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		433	45	33	511
5. Cats		705	303		1008
6. Guinea Pigs	80	281	912	432	1625
7. Hamsters	-	3869	451	4155	8475
8. Rabbits	34	10	1447	476	1933
9. Non-human Primates					
10. Sheep					
11. Pigs		2418			2418
12. Other Farm Animals					
CATTLE		2228			2228
13. Other Animals					
HORSE	54	315			315

ASSURANCE STATEMENTS

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

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

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

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

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

SIGNAT

DATE SIGNED 11/2/03

APHIS F
(AUG 91)

Customer ID and Site Address:

ID: 27

431 County Road
Millsboro, DE 19966
County: Sussex

Telephone

Customer ID and Site Address:

ID: 27

35500 West 91st Street
De Soto, KS 66018
County: Johnson

Telephone

Customer ID and Site Address:

ID: 27

12707 Shawnee
Mission Parkway
Shawnee, KS 66216
County: Johnson

Telephone

Customer ID and Site Address:

ID: 27

902 Sugar Grove
Avenue
Dallas Center, IA 50063
County: Dallas

Telephone

Customer ID and Site Address:

ID: 27

Bldg 24
717 Highway 59/60
South
Worthington, MN 56187
County: Nobles

Telephone

Customer ID and Site Address:

ID: 27

27480 King Avenue
Rushmore, MN 56168
County: Nobles

Telephone

Column E Explanation

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

1. Registration Number: 50-R-003

2. Number 11 of animals used in this study.

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

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

Following CPV challenge in non-vaccinated animals, clinical signs include leukopenia, depression, pyrexia, vomiting, admominal pain and diarrhea. Clinical signs are required in control animals in order to determine vaccine efficacy.

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

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

Agency APHIS CFR 113.317

Column E Explanation

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

1. Registration Number: 50-R-0003

2. Number 11 of animals used in this study.

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

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

Clinical signs are required in control animals in order to determine vaccine efficacy. Clinical signs after challenge may include, depression, serious mucopurulent conjustivitis, coughing vomiting and tenesmus.

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

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

Agency APHIS CFR 113.306

Column E Explanation

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

1. Registration Number: 50-R-003

2. Number 11 of animals used in this study.

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

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

Following challenge in non-vaccinated animals, clinical signs may include depression, coughing, vomiting or diarreaha. Clinical signs are required in control animals in order to determine vaccine efficacy.

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

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

Agency APHIS CFR 113.305

Column E Explanation

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

1. Registration Number: 50-R-003

2. Number 432 of animals used in this study.

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

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

All 432 Guinea Pigs were used for testing as specified in 9CFR. All clinical signs and death are required when inoculated with Clostridium chauvoei.

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

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

Agency APHIS CFR 113.106

Column E Explanation

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

1. Registration Number: 50-R-0003

2. Number 4155 of animals used in this study.

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

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

All hamsters were used for testing as stated by 9CFR. Death is the end point.

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

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

Agency APHIS CFR 113.101, 113.102, 113.103, 113.104, 113.105

Column E Explanation

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

1. Registration Number: 50-R-003

2. Number 476 of animals used in this study.

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

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

All 476 rabbits were challenged with Clostridium Septicum. Pain and distress are due to the disease processes associated with the challenge. Animals are allowed to go 72 hours, when test results are interpreted.

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

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 CVB CFR 9CFR 133.5

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

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 50-R-0004 **CUSTOMER NO.** 42

FORM APPROVED
OMB NO. 0579-0036

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

ASTRA ZENECA PHARMACEUTICALS
VETERINARY MEDICINE DEPT
P.O. BOX 15437 (1800 CONCORD PIKE)
WILMINGTON, DE 19850-5437

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)*

ZENECA BIOMEDICAL RESEARCH
WILMINGTON, DE 19850-5437

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		26		32	58
5. Cats					
6. Guinea Pigs		427	417	73	917
7. Hamsters					
8. Rabbits			4		4
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
ferret			229	58	287
gerbil		11	472		483

ASSURANCE STATEMENTS

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

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

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

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

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/14/2003

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

PART 1 - HEADQUARTERS

APHIS Form 7023 Column E Explanation

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

---

1. Registration Number: 50-R-0004

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

ferret (58)

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

Studies in ferrets are to evaluate whether candidate drugs have either emetic or anti-emetic properties. Animals are dosed with an emetic followed by and experimental compound and then videotaped for a period of time after dosing. Videotapes are read and scored for episodes of emesis and related behaviors.

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

Animals in this category are given an emetic agent which causes vomiting and retching. The objective of these studies is to determine experimental compounds' effects on the emetic response. In order to evaluate this effect, we cannot alleviate these distress reponses (retching, vomiting) with drugs that would confound the measurements.

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

Agency: CFR:

APHIS Form 7023 Column E Explanation

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

---

1. Registration Number: 50-R-0004

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

Guinea Pigs (73)

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

This study is used to evaluate experimental compounds for suppression of isolation-induced vocalizations in guinea pig pups. Various antidepressant and anxiolytic drugs, acutely administered before transient maternal separation, have been reported to dose-dependently and completely inhibit separation-induced vocalizations is this species. Experimental compounds ability to suppress vocalizations is compared with that of clinically used antidepressants and anxiolytics.

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

This study is designed to assess compounds in an animal model of human affective disorders. This animal model is based on separation-induced distress; therefore, alleviation of distress would make this behavioral assay invalid.

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

Agency: CFR:

APHIS Form 7023 Column E Explanation

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

---

1. Registration Number: 50-R-0004

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

Dogs (32)

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

Single and Repeat dose toxicity studies are performed in dogs. Animals are dosed with experimental compounds and observed for drug related adverse clinical signs.

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

Single and Repeat dose toxicity studies are now required by worldwide regulatory agencies as part of the New Drug Application submission package. This type of study in the dog is extremely useful because it usually requires a small number of animals and provides valuable information on acute toxic effects and drug related adverse clinical signs. Providing relief of any drug related adverse effects would defeat the purpose of the safety assessment study. Determining the safety profile of a compound at the early stage of drug development minimizes the need for larger scale studies in future stages of drug development.

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

Agency: CFR:

OCT 14 2003

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 50-R-0006
CUSTOMER NUMBER: 45

FORM APPROVED
OMB NO. 0579-0036

University Of Delaware
Office Of Lab Animal Medicine
020 Wolf Hall
Newark, DE 19716

Telephone: (302) -831-2980

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

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

ASSURANCE STATEMENTS

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

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

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

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

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

SIG

DATE SIGNED 10/6/03

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

University of Delaware
Office of Lab Animal Medicine
056 McKinly Lab
Newark, DE 19716

Certificate Number: 50-R-0006
Customer Number: 45

FACILITY LOCATIONS (Sites)

- 020 Wolf Hall
- 046 McKinly Lab
- 133-138 Wolf Hall

10/6/03
Date

DEC 1 7 2003

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 50-R-0009
CUSTOMER NUMBER: 47

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Nemours Foundation, The
Alfred I. Dupont Hospital For Children
1600 Rockland Rd
Wilmington, DE 19899

Telephone: (302) -651-6860

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

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

ASSURANCE STATEMENTS

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

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

DATE SIGNED
10/7/03

NOV 21 2005

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 50-R-0013
CUSTOMER NUMBER: 9014

FORM APPROVED
OMB NO. 0579-0036

Strategic Diagnostics Inc.
128 Sandy Drive
Newark, DE 19713

Telephone: (302) -456-6785

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

FACILITY LOCATIONS (Sites) - See Atached Listing 52 Anderson Road, Windham, M

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	2	46	0	0	46
7. Hamsters	0	12	0	0	12
8. Rabbits	3,499	13,940	174	0	14,114
9. Non-human Primates					
10. Sheep	0	49	0	0	49
11. Pigs					
12. Other Farm Animals					
Goats	46	353	18	0	371
13. Other Animals					

ASSURANCE STATEMENTS

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL

APHIS FC
(AUI