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

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 22-R-0001
CUSTOMER NUMBER: 158

FORM APPROVED
OMB NO. 0579-0036

Bell Labs Lucent Technologies
600 Mountain Avenue
P. O. Box 636
Murray Hill, NJ 07974

Telephone: (908) -582-5696

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

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

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

3) This facility is adhering to the standards and 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
		1/20/04

APHIS FORM 7023
(AUG 91)

(Replaces VS FORM 10-23 (OCT 88), which is obsolete.)

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 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: 22-R-0005
CUSTOMER NUMBER: 8203

FORM APPROVED
OMB NO. 0579-0036

N J State Dept Of Health
Div. Of Pub Health & Env. Labs
Cn 360
Trenton, NJ 08625

SEP 29 2003

Telephone: (609) - 292-5847

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)

LAB BLDG. - PH+EL

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 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					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

N/A

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)

DATE SIGNED
9/25/03

APHIS FORM 7023 (AUG 91)

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

NOV 2 6 2003

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

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0006
CUSTOMER NUMBER: 169

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Ortho Pharmaceutical Corporation
Johnson & Johnson Pharmaceutical Rsrch & Dev, L.L.C.
P O Box 300 Route 202 South
Raritan, NJ 08869

Telephone: (908) -704-4310

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	50	370*	197*	34*	601
5. Cats	-	-	-	-	-
6. Guinea Pigs	12	729*	795*	30	1554
7. Hamsters	20	0	661*	446	1107
8. Rabbits	5*	0	183*	0	183
9. Non-human Primates	14*	16*	52*	0	68
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

DATE SIGNED
11-25-03

ATTACHMENT 1

USDA ANNUAL REPORT (2002-2003)

Registration #: 22-R- 0006

The following animals were reported on previous USDA Reports under License: 22-R-0006.

SPECIES	CATEGORY B	CATEGORY C	CATEGORY D	CATEGORY E
DOGS	0	170	154	18
GUINEA PIGS	0	8	141	0
HAMSTERS	0	0	122	0
RABBITS	5	0	53	0
NON-HUMAN PRIMATES	12	11	52	0

ATTACHMENT 2

USDA ANNUAL REPORT (2002-2003)

Registration #: 22-R- 0006

Animals Listed in Category E

During the reporting period, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Institutional Animal Care and Use Committee (IACUC) approved the use of animals in Category E as follows:

SPECIES	NUMBER	PROCEDURE/JUSTIFICATION
Dogs	34	Single and repeat dose Pharmacokinetic/Toxicology studies as part of the Preclinical package submitted to the FDA for review and eventual drug approval. In these studies, animals may occasionally show mild emesis and short-term loss of appetite. It is important to determine if these clinical signs are reversible, as is often the case. Opioid analgesics alter GI motility and would be contraindicated. 1,2, 3
Guinea Pigs	30	Animals involved in studies on delayed hypersensitivity and anaphylaxis. These animals (controls) are used to evaluate potential asthma treatments and are thus exposed via aerosol to agents that cause mild, transient bronchospasm. 1
Hamster	446	Studies are used for evaluating anti-inflammatory compounds. Dorsal sub-cutaneous air pouch and paw edema models are utilized. 1

1 Administration of anesthetics, analgesics or tranquilizing drugs must be withheld so as not to invalidate the evaluation of test compounds.

2 Preclinical toxicology and drug metabolism/pharmacokinetic studies are required in nonhuman species by the Food and Drug Administration, Good Laboratory Practice Regulations – CFR 21, Part 58 (Code of Conduct).

3 Spied, L.H., Lunley, C.E. and S.R. Walker. "Harmonization of Guidelines for Toxicity Testing of Pharmaceuticals by 1992." Regulatory Toxicology and Pharmacology. Vol 12, pp 179-211 (1990).

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!

DEC 01 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: 22-R-0009
CUSTOMER NUMBER: 519

FORM APPROVED
OMB NO. 0579-0036

Novartis Pharmaceuticals Corporation
Bldg 437/1329
One Health Plaza
East Hanover, NJ 07936

Telephone: (973) -781-0074

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	42	424	41	92	557
5. Cats					
6. Guinea Pigs					
7. Hamsters		876	7		883
8. Rabbits	9	522	52	47	621
9. Non-human Primates	210	344	69	52	465
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

DATE SIGNED
11-26-03

OPTIONAL COLUMN E EXPLANATION FORM

ORAL (GAVAGE) RISING DOSE/2-WEEK TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 4. Number of animals classified as category "E" - 2.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Two dogs on this study experienced compound related effects and were euthanized unscheduled.

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

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

INTRAVENOUS RISING DOSE TOXICITY STUDY IN DOGS WITH A 17-DAY RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 6. Number of animals classified as category "E" - 1.

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

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

   These dogs were dosed with a pharmaceutical compound.

   One dog on this study experienced compound related effects.

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

   The clinical signs were not deemed so severe that intervention was necessary. This animal remained on study.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

52-WEEK ORAL (CAPSULE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 40. Number of animals classified as category "E" - 22.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Twenty two dogs experienced compound related effects such as diarrhea and emesis.

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

   The signs were not considered to be so severe that intervention was necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

26-WEEK ORAL (CAPSULE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 38. Number of animals classified as category "E" – 10.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Ten dogs experienced compound related effects such as diarrhea primarily.

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

   The signs were not considered to be so severe that intervention was necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

26-WEEK ORAL (CAPSULE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 40. Number of animals classified as category "E" - 13.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Thirteen dogs experienced compound related effects in this study. One was euthanized unscheduled and the signs for the others were not considered to be so severe that intervention was necessary.

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

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

ORAL (GAVAGE) RISING DOSE/1-WEEK TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 6. Number of animals classified as category "E" - 5.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Five dogs experienced compound related effects in this study and were euthanized unscheduled.

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

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

INTRAVENOUS RISING DOSE TOXICITY STUDY IN DOGS WITH A 16-DAY RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 4. Number of animals classified as category "E" - 1.

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

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

   These dogs were dosed with a pharmaceutical compound.

   One dog experienced compound related effects in this study. This dog was euthanized on study day one.

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

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

ORAL (GAVAGE) RISING DOSE/1-WEEK TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 6. Number of animals classified as category "E" - 6.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Six dogs experienced compound related effects such in this study. One dog was found dead on study day 5 and three other dogs were euthanized unscheduled on study day 5. Two dogs were euthanized unscheduled on study days 7 and 9.

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

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

ACUTE ORAL (GAVAGE) TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 6. Number of animals classified as category "E" - 4.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Four dogs on this study experienced compound related effects and were euthanized unscheduled.

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

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 32. Number of animals classified as category "E" - 2.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Two dogs experienced compound related effects such as diarrhea for more than 3-4 days in this study.

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

   The diarrhea resolved and intervention was not deemed necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

EXPLORATORY 4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN FEMALE DOGS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 8. Number of animals classified as category "E" - 1.

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

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

   These dogs were dosed with a pharmaceutical compound.

   One dog on this study experienced compound related effects. It had diarrhea for more than one week.

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

   The signs were not considered to be so severe that intervention was necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 32. Number of animals classified as category "E" - 10.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Ten dogs experienced compound related effects in this study. The effects included diarrhea, ataxia and emesis greater than 3 days duration. One dog was euthanized unscheduled.

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

   The signs for the others were not considered to be so severe that intervention was necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN DOGS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 32. Number of animals classified as category "E" - 11.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Eleven dogs experienced compound related effects such as diarrhea and emesis. Four were euthanized unscheduled.

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

   The signs for the others were not considered to be so severe that intervention was necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

ORAL (GAVAGE) RISING DOSE TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 6. Number of animals classified as category "E" - 1.

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

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

   These dogs were dosed with a pharmaceutical compound.

   One dog experienced compound related effects in this study.

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

   The animal was found dead.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

2-WEEK ORAL (GAVAGE) TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 24. Number of animals classified as category "E" - 3.

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

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

   These dogs were dosed with a pharmaceutical compound.

   Three dogs on this study experienced compound related effects. They had emesis on more than 7 days of the study.

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

   The signs were not considered to be so severe that intervention was necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

   1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

INTRAVENOUS RISING DOSE TOXICITY STUDY IN MONKEYS WITH A 16-DAY RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 8. Number of animals classified as category "E" - 5.

3. Species (common name)___Non-human Primate___ of animals used in this study.

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

   These primates were dosed with a pharmaceutical compound.

   Five monkeys experienced skin irritations and lesions as a compound related effect.

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

   The lesions were treated topically or were not considered so severe that interventions was necessary.

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):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN MONKEYS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 32. Number of animals classified as category "E" - 1.

3. Species (common name)___Non-human Primate___ of animals used in this study.

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

   These primates were dosed with a pharmaceutical compound.

   This monkey experienced decreased locomotor activity, dehydration and emesis as compound related effects. This monkey also experienced the compound related effect of emesis on seven of thirty days on study. Five of the seven days occurred within the same week.

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

   The purpose of this study was to determine the toxicity of the compound. In these cases, the relief of pain and/or distress would have defeated the purpose of the study.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

4-WEEK ORAL (GAVAGE) TOXICITY STUDY IN MONKEYS WITH A 4-WEEK RECOVERY

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 32. Number of animals classified as category "E" - 8.

3. Species (common name)___Non-human Primate___ of animals used in this study.

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

   These primates were dosed with a pharmaceutical compound.

   Eight monkeys on this study experienced compound related effects. One was found dead, two were euthanized unscheduled and for the other five the clinical signs were not considered so severe that intervention was necessary.

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

   As soon as there were signs that animals were experiencing significant pain and distress they were euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

39-WEEK ORAL (GAVAGE) TOXICITY STUDY IN MONKEYS WITH A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 40. Number of animals classified as category "E" - 9.

3. Species (common name)___Non-human Primate___ of animals used in this study.

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

   These primates were dosed with a pharmaceutical compound.

   Nine monkeys experienced compound related effects on this study. One animal was found dead and seven were euthanized unscheduled. For one animal, the clinical signs were not deemed so severe that intervention was necessary. This animal is still on study.

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

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

10-DAY ORAL (GAVAGE) DOSE ESCALATION STUDY IN MARMOSETS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 12. Number of animals classified as category "E" - 6.

3. Species (common name)___Non-human Primate___ of animals used in this study.

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

   These primates were dosed with a pharmaceutical compound.

   Six marmosets on this study experienced the compound related effect of emesis for more than three consecutive days.

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

   The purpose of this study was to determine the toxicity of the compound. In these cases, the relief of the emesis would have defeated the purpose of the study. Therefore the degree of distress experienced was justifiable.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

1-WEEK ORAL (GAVAGE) TOXICITY STUDY IN MARMOSETS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 16. Number of animals classified as category "E" - 1.

3. Species (common name)____Non-human Primates___ of animals used in this study.

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

   These primates were dosed with a pharmaceutical compound.

   One marmoset experienced compound related effects in this study. This marmoset had diarrhea with some blood in it for 3-4 days.

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

   Intervention was not deemed necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

2-WEEK ORAL (GAVAGE) DOSE RANGE-FINDING TOXICITY STUDY IN MARMOSETS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 24. Number of animals classified as category "E" - 4.

3. Species (common name)____Non-human Primates___ of animals used in this study.

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

   These animals were dosed with a pharmaceutical compound.

   Four marmosets experienced compound related effects. Three of the four had emesis more than 3 days consecutively. One had decreased locomotor activity and poor body condition and had to be euthanized unscheduled on day 15 of dosing.

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

   The purpose of this study was to determine the toxicity of the compound. As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

4-WEEK NASOGASTRIC (GAVAGE) TOXICITY/COMBINATION STUDY IN MONKEYS WITH NEORAL® AND A 4-WEEK RECOVERY PERIOD

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 44. Number of animals classified as category "E" - 6.

3. Species (common name)____Non-human Primates___ of animals used in this study.

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

   These animals were dosed with a pharmaceutical compound.

   Six monkeys on this study experienced compound related effects. One was found dead and the clinical signs for the others were not considered so severe that intervention was necessary.

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

   The clinical signs for five monkeys were not considered so severe that intervention was necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

OPTIONAL COLUMN E EXPLANATION FORM

2-WEEK ORAL (GAVAGE) DOSE RANGE-FINDING STUDY IN MONKEYS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 10. Number of animals classified as category "E" - 2.

3. Species (common name)____Non-human Primates___ of animals used in this study.

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

   These animals were dosed with a pharmaceutical compound.

   Two cynomolgus monkeys experienced the compound related effects of decreased food consumption, decreased locomotor activity, abnormal posture, ataxia and recumbency. They were euthanized on day 5 and 12.

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

   It was determined that the degree of pain and/or distress recognized in the monkeys justified unscheduled euthanasia.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

OPTIONAL COLUMN E EXPLANATION FORM

INTRAVENOUS DOSE RANGE-FINDING STUDY IN MONKEYS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 10. Number of animals classified as category "E" - 4.

3. Species (common name)____Non-human Primates___ of animals used in this study.

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

   These animals were dose with a pharmaceutical compound.

   Four Cynomolgus monkeys on this study experienced compound related effects. One was found dead on day 8 of dosing and the other three were euthanized unscheduled, two on study day 3 and one on study day 9.

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

   The purpose of this study was to determine the toxicity of the compound. As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

OPTIONAL COLUMN E EXPLANATION FORM

2-WEEK NASOGASTRIC (GAVAGE) DOSE RANGE-FINDING COMBINATION STUDY IN MALE MONKEYS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 12. Number of animals classified as category "E" - 4.

3. Species (common name)____Non-human Primates___ of animals used in this study.

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

   These animals were dosed with a pharmaceutical compound.

   Four monkeys experienced compound related effects. One was found dead and three were euthanized unscheduled.

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

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

OPTIONAL COLUMN E EXPLANATION FORM

ORAL (GAVAGE) RISING DOSE TOXICITY STUDY IN MONKEYS

1. Registration Number: 22-R-0009

2. Number of animals used in this study –2. Number of animals classified as category "E" - 2.

3. Species (common name)____Non-human Primates___ of animals used in this study.

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

   These animals were dosed with a pharmaceutical compound.

   The two monkeys on this study experienced compound related effects. The monkeys were euthanized after they were observed in a moribund condition.

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

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

OPTIONAL COLUMN E EXPLANATION FORM

ORAL EMBRYO-FETAL DEVELOPMENT STUDY IN RABBITS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 80. Number of animals classified as category "E" - 23.

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

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

   These animals were dosed with a pharmaceutical compound.

   Twenty-three rabbits in this study experienced compound related effects. One was found dead and the others had ataxia and some recumbency.

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

   The signs were not considered to be so severe that intervention was necessary.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

OPTIONAL COLUMN E EXPLANATION FORM

ORAL EMBRYO-FETAL DEVELOPMENT DOSE RANGE-FINDING STUDY IN RABBITS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 30. Number of animals classified as category "E" - 1.

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

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

   These animals were dosed with a pharmaceutical compound.

   One rabbit in this study experienced compound related effects and was euthanized after it was observed in a moribund condition.

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

   As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

OPTIONAL COLUMN E EXPLANATION FORM

EMBRYO-FETAL DEVELOPMENT STUDY IN RABBITS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 80. Number of animals classified as category "E" - 1.

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

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

   These animals were dosed with a pharmaceutical compound.

   One rabbit in this study experienced a compound related effect. This rabbit was euthanized after being found recumbent with labored breathing.

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

   This animal was euthanized once signs indicating pain and distress were observed.

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):

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

OPTIONAL COLUMN E EXPLANATION FORM

ORAL EMBRYO-FETAL DEVELOPMENT DOSE RANGE FINDING STUDY IN RABBITS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 30. Number of animals classified as category "E" - 6.

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

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

   These animals were dosed with a pharmaceutical compound.

   Six animals on this study experienced compound related effects. Five were found dead and one was euthanized unscheduled.

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

   As soon as signs of pain or distress were observed, the animals were euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

OPTIONAL COLUMN E EXPLANATION FORM

ORAL EMBRYO-FETAL DEVELOPMENT DOSE RANGE FINDING STUDY IN RABBITS

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 15. Number of animals classified as category "E" - 15.

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

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

   These animals were dosed with a pharmaceutical compound.

   Fifteen rabbits on this study experienced compound related effects. Six were found dead and the others were euthanized unscheduled.

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

   As soon as signs of pain or distress were observed, the animals were euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

OPTIONAL COLUMN E EXPLANATION FORM

2-CYCLE INTRAVENOUS EMBRYO-FETAL DEVELOPMENT DOSE RANGE-FINDING STUDY

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 15. Number of animals classified as category "E" - 6.

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

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

   These animals were dosed with a pharmaceutical compound.

   Six rabbits experienced compound related effects during the 2003 reporting year. One animal was found dead and the others were euthanized unscheduled.

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

   As soon as signs of pain or distress were observed, the animals were euthanized.

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

   The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

USDA ANNUAL REPORT OF RESEARCH FACILITY FOR 2003
NOVARTIS PHARMACEUTICALS CORPORATION
USDA Registration No. 22-R-0009

Summary of the NACUC approved exceptions to the Standards and Regulations:
Canine Exercise Exemptions

	Protocol Title	Species	Number	Days Without Exercise	Reason
1.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	08	7	Quantitative collection of excreta, containment of radioactivity
2.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	07	4	Quantitative collection of excreta, containment of radioactivity
3.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	02	9	Quantitative collection of excreta, containment of radioactivity
4.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	42	15	Treatment of Giardia
5.	Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog	Dogs	01	30	Possible Transmissible Infection
6.	Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies	Dogs	2	14	Surgical recovery of dogs implanted with telemetry devices

	Protocol Title	Species	Number	Days Without Exercise	Reason
7.	Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies	Dogs	5	12	Surgical recovery of dogs implanted with telemetry devices
8.	Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies	Dogs	7	10	Surgical recovery of dogs implanted with telemetry devices
9.	Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies	Dogs	1	13	Surgical recovery of dogs implanted with telemetry devices

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!

DEC 01 2003

See attached form for additional information.

Interagency Report Control No.: RSM

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 22-R-0013

CUSTOMER NUMBER: 163

FORM APPROVED
OMB NO. 0579-0036

Worldwide Mobile Veterinary Unit
8 Foxhunt Drive
Rockaway, NJ 07866

Telephone: (973) -361-5428

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

ASSURANCE STATEMENTS

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

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

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

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

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

DATE SIGNED
11/24/03

(AUG 91)

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21! NOV 21 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: 22-R-0016
CUSTOMER NUMBER: 174

FORM APPROVED
OMB NO. 0579-0036

Johnson & Johnson Consumer Products,Inc.
Johnson & Johnson Res. Found.
Research & Development
199 Grandview Road
Skillman, NJ 08558

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

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

ASSURANCE STATEMENTS

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

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

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/19/03

(AUG 91)

NOV 2 6 2003

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

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0020
CUSTOMER NUMBER: 175

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

University Of Medicine & Dentistry Of New Jersy
New Jersey Medical School
185 S. Orange Avenue
Msb A-604
Newark, NJ 07101

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use 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			41		41
5. Cats			6		6
6. Guinea Pigs		15			15
7. Hamsters		5	25		30
8. Rabbits		2	124		126
9. Non-human Primates			8		8
10. Sheep					
11. Pigs			94		94
12. Other Farm Animals					
13. Other Animals					
Woodchucks			23		23

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 11/20/03

APHIS Form 7020 (Replaces VS Form 18-20 (OCT 88), which is obsolete.)
(AUG 91)

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

DEC 0 1 2003

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0022
CUSTOMER NUMBER: 176

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Princeton University
Office Of Research & Projects
P.O. Box 36
Princeton, NJ 08544

Telephone: (609) -258-3090

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 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					
5. Cats			16		16
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			33		33
9. Non-human Primates	3	6	16		22
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Marmosets			37		37

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

S

DATE SIGNED
11/25/03

AF

(AUG 91)

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

See attached form for additional information.

Interagency Report Control No.: R5M

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0025
CUSTOMER NUMBER: 177

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Rutgers-State University Of Nj
Research & Sponsored Programs
3 Rutgers Plaza
New Brunswick, NJ 08901

DEC 05 2003

Telephone: (732) -932-0150

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	16		58		58
5. Cats			27		27
6. Guinea Pigs		409	251		660
7. Hamsters					
8. Rabbits	14	4	10		14
9. Non-human Primates			5		5
10. Sheep					
11. Pigs			8		8
12. Other Farm Animals					
Deer		22			22
13. Other Animals					
Ferrets		2			2
Gerbils		38			38
Spiny Mice		2			2

ASSURANCE STATEMENTS

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

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

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

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

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

S

E SIGNED
-26-03

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

Customer ID and Site Address:

ID: 177

3559d Nelson Labs &
Annex
604 Allison Road
Piscataway, NJ 08854
County: Middlesex

Telephone

Customer ID and Site Address:

ID: 177

P.O. Box 1059
Bldg 7002 Science
Camden, NJ 08101
County: Camden

Telephone

Customer ID and Site Address:

ID: 177

Psarf Complex &
Bartlett Hall
New Brunswick, NJ 08901
County: Middlesex

Telephone

Customer ID and Site Address:

ID: 177

197 University Avenue
Newark, NJ 07102
County: Essex

Telephone

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!

DEC 01 2003

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0030
CUSTOMER NUMBER: 178

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Merck & Company, Inc.
126 E Lincoln Avenue
Po Box 2000 Ry80m-101
Rahway, NJ 07065

Telephone: (732) -594-3430

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 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 appfopriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	3	749	1061	1	1811
5. Cats	0	35	0		35
6. Guinea Pigs	66	2288	467		2755
7. Hamsters	59	377	65		442
8. Rabbits	18	2440	873	66	3379
9. Non-human Primates	3778	188	877		1065
10. Sheep					
11. Pigs	20	39	88		127
12. Other Farm Animals					
Horses	1	1	3		4
13. Other Animals					
Ferrets		24	200		224
Gerbils		0	32		32

ASSURANCE STATEMENTS

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

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

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ac 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 11/22/03

APHIS F(
(AUG 91)

CIGN

USDA Annual Report: October 1, 2002-September 30, 2003

Registration Number 22-R-0030; Merck & Co., Inc

This report includes animals housed or used at the following sites:

126 E. Lincoln Avenue
Rahway NJ 07065-4607
COUNTY: UNION
Telephone:
(732) 594-6179

203 River Rd
Somerville NJ 08876
COUNTY: SOMERSET
Telephone:
(908) 685-3846

RD 1 Box 391
Oxford NJ 07863
COUNTY: WARREN
Telephone:
(908) 637-4427
(Inactivated September 17, 2003)

3535 General Atomics Ct
San Diego CA 92121-1140
COUNTY: SAN DIEGO
Telephone:
(858) 202-5466

WP44-201
West Point PA 19486-0004
COUNTY: MONTGOMERY
Telephone:
(215) 652-6232

WP74-1
West Point PA 19486-0004
COUNTY: MONTGOMERY
Telephone:
(215) 652-6093

PO Box 016960 (R289)
Miami FL 33136
COUNTY: DADE
Telephone:
(305) 243-8912
(Inactivated April 16, 2003)

20256 SW 360th St
Homestead FL 33034-4102
COUNTY: DADE
Telephone:
(305) 245-1551

PO Box 549
Alice TX 78333
COUNTY: JIM WELLS
Telephone:
(361) 664-4984
(Inactivated April 16, 2003)

95 Castle Hall Road
Yemassee SC 29945
COUNTY: BEAUFORT
Telephone:
(843)589-5190
(Inactivated April 16, 2003)

466 Devon Park Drive
Wayne PA 19087
COUNTY: CHESTER
Telephone:
(215) 652-6232

New Iberia Research Center
University of Louisiana
4401 W. Admiral Doyle Drive
New Iberia LA 70560
COUNTY: IBERIA
Telephone:
(337) 482-0250
(Inactivated April 16, 2003)

Explanation of items in column E:

One dog experienced unanticipated distress for less than one hour after oral test compound administration for an IACUC-approved research protocol. The dog was examined by a veterinarian and subsequently euthanized. The use of anesthetics, analgesics or tranquilizers would have adversely affected the interpretation of results.

Studies were conducted in rabbits to evaluate the efficacy of novel antibacterial compounds. After being administered a known microbial agent, sixty-six rabbits experienced mild to moderate discomfort for less than 8 hours. Established antibacterial compounds and pain-relieving agents could not be administered because they would prevent assessment of the experimental compounds and defeat the purpose of the research. The minimum numbers of animals were used to provide reliable test results. These procedures were reviewed and approved by the IACUC and monitored by a veterinarian.

USDA Annual Report: October 1, 2002-September 30, 2003

Registration Number 22-R-0030; Merck & Co., Inc

IACUC-approved exceptions to the standards and regulations:

One dog was exempted from the approved dog exercise plan because it was being treated and observed during a post-operative period that lasted for five days.

Nine dogs were exempted from the approved dog exercise plan because they required urine/feces collection for five days after radioactive isotopes were administered.

One dog was exempted from the approved dog exercise plan on two occasions because it required urine/feces collection for five days after radioactive isotopes were administered. The animal was provided with the opportunity to exercise for 24 hours between the first occasion for exemption and the second occasion for exemption.

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: 22-R-0031
CUSTOMER NUMBER: 179

FORM APPROVED
OMB NO. 0579-0036

Newark Beth Israel Medical Center
201 Lyons Avenue
Newark, NJ 07112

Telephone: (973) 926-7311

OCT 24 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	7		52		52
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs	0		14		14
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

SI(

DATE SIGNED
10/22/03

AP

(AUG 91)

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

NOV 2 8 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: 22-R-0032
CUSTOMER NUMBER: 180

FORM APPROVED
OMB NO. 0579-0036

Hoffmann-La Roche, Inc.
Research & Development Div.
340 Kingsland Street
Nutley, NJ 07110

Telephone: (973) -235-5000

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	63	294	5	0	299
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	5	10	0	15
7. Hamsters	0	0	0	0	0
8. Rabbits	0	239	1	5	245
9. Non-human Primates	34	18	16	0	34
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

SIG

DATE SIGNED 11/24/03

APHIS FORM 7023
(AUG 91)

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

Column E Explanation

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

1. Registration Number: 22-R-0032

2. Number _____ of animals used in this study.

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

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

   A total of 5 rabbits from a group used in studies to evaluate drug candidates for clinical trials were identified as Category E. The rabbits were used to evaluate a HIV inhibitor compound and found dead without prior clinical signs.

   The studies were designed and conducted in accordance with the FDA guidelines. Veterinary personnel observed all animals daily and provides supportative care when needed.

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 FDA CFR 58.1

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

DEC 0 8 2003

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: 22-R-0037
CUSTOMER NUMBER: 752

FORM APPROVED
OMB NO. 0579-0036

Rider University
2083 Lawrenceville Road
Lawrenceville, NJ 08648

Telephone: (609) -896-5010

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 Science & Technology Center - Room S-151

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
spiny mice		275			275

ASSURANCE STATEMENTS

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

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

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

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

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

SIGI

DATE SIGNED
12/1/03

APHI

(AUG 91)

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

DEC 10 2003

See attached form for additional information.

Interagency Report Control No.: 40

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0038
CUSTOMER NUMBER: 677

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Bracco Research Usa, Inc.
305 College Road East
Princeton, NJ 08540

Telephone: (609) -514-~~2437~~ 2524 or -2409 pp

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 Same address as above.

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use 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	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals			(Only rats and mice bred for research used)		

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)

DATE SIGNED Dec 03

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

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21. NOV 20 2003 See attached form for additional information. Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0040
CUSTOMER NUMBER: 689

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Huntingdon Life Sciences, Inc.
P.O. Box 2360
East Millstone, NJ 08875

Telephone: (732) -873-2550

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 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	19	180	128	9	317
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	113	24	7	144
9. Non-human Primates	62	229	86	28	343
10. Sheep					
11. Pigs	0	68	6	0	74
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

DATE SIGNED
11/19/03

192

Annual Report of Research Facility
October 1, 2002 to September 30, 2003
Huntingdon Life Sciences
Registration Number 22-R-0040

A) Explanation of Category E Studies

All studies listed were conducted to conform to federally mandated requirements, promulgated by the US Food and Drug Administration (FDA). These regulations specify preclinical testing requirements necessary for approval of new drugs. Specific regulations include the following:

- 21 CFR 310, New Drugs
- 21 CFR 312.22, Investigational New Drugs/Biologics
- 21 CFR 314, Application for FDA Approval to Market a New Drug or Antibiotic Drug
- M3 Nonclinical Safety Studies for the Conduct of Clinical Trials in Pharmaceuticals – Guidance for Industry, US Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), July 1997
- Guidelines for General Pharmacology Studies (Japan Ministry of Health, Labor and Welfare PAB/NDD Notification No. 4, 29 January 1991)
- International Conference on Harmonization (ICH) Guideline Topic S7, Safety Pharmacology

For all studies listed below, the Principal Investigator provided written justification to the Huntingdon Life Sciences Institutional Animal Care and Use Committee that agents may not be used to alleviate pain or distress due to their potential for interference with the compound under investigation. Use of these agents was withheld so as not to invalidate the evaluation of test compounds, which could result in unnecessary duplication of research, and use of animals in number beyond that which is minimally required.

Species	Number of Category E Animals	Description
Rabbits	7	Animals were exposed to test compound via oral administration, for 14 days. Test article effects were evident in 7 animals. Affected animals were humanely euthanized.
Dogs	5	Animals were exposed to test compound via oral administration, for 28 days. Test article effects were evident in 5 animals. Affected animals were humanely euthanized.
Dogs	2	Animals were exposed to test compound via intravenous administration once. Test article effects were evident in 2 animals. Dose was discontiunued in both affected animals.
Dogs	2	Animals were exposed to test compound via intravenous administration once. Test article effects were evident in 2 animals. Both affected animals animals were humanely euthanized.
Primate	8	Animals were exposed to test compound via intravenous administration for 8 days. Test article effects of brief duration resolved spontaneously in 8 affected animals.
Primate	1	Animals were exposed to test compound via intravenous administration, once per week for 4 weeks. Test article effects of brief duration resolved spontaneously in 1 affected animal.

Annual Report of Research Facility
October 1, 2002 to September 30, 2003
Huntingdon Life Sciences
Registration Number 22-R-0040

Species	Number of Category E Animals	Description
Primate	10	Animals were exposed to test compound via oral administration for 28 days. Test article effects were evident in 10 animals. Four of the affected animals were humanely euthanized.
Primate	7	Animals were exposed to test compound via intravenous administration, four times over a 2-week period. Test article effects of brief duration resolved spontaneously in 7 affected animals.
Primate	2	Animals were exposed to test compound via oral administration for 28 days. Test article effects were evident in 2 animals. Both affected animals were humanely euthanized.

B) Summary of IACUC-approved exceptions to the Standards and Regulations:

- 13 dogs were exempted from the exercise requirement for 18 days during surgical recovery and data collection via subcutaneous telemetry implant.
- 14 dogs were exempted from the exercise requirement for 10 days during surgical recovery and 12 of these dogs were also exempted from the exercise requirement for an additional 9 days during data collection via subcutaneous telemetry implant.
- 6 dogs were exempted from the exercise requirement for 5 days during surgical recovery.
- 14 dogs were exempted from the exercise requirement for 10 days due to surgical recovery and 12 of these dogs were also exempted from the exercise requirement for an additional 29 days during data collection via subcutaneous telemetry implant.
- 59 dogs were exempted from the exercise requirement for 21 days during surgical recovery.

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: 22-R-0041
CUSTOMER NUMBER: 173

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Becton Dickinson And Co.
One Becton Drive
Franklin Lakes, NJ 07417

Telephone: (201) -847-6800

DEC 17 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 necessarv or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0				0
5. Cats	0				0
6. Guinea Pigs	0	1730			1730
7. Hamsters	0				0
8. Rabbits	0	289	18		307
9. Non-human Primates	0				0
10. Sheep	0				0
11. Pigs	0		579		579
12. Other Farm Animals	0				0
13. Other Animals	0				0

ASSURANCE STATEMENTS

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

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

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

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

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

S

SIGNED

AI

30 Oct. 03

Customer ID and Site Address:

ID: 173

21 Davis Drive
Research Triangle Pa, NC 27709
County: Durham

Telephone
(919)597-6151

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

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 21-R-0061
CUSTOMER NUMBER: 322

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Hobart And William Smith Colleges
Eaton Hall Biology Dept
Geneva, NY 14456

Telephone: (315) -781-3586

OCT 06 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					
5. Cats		24 preserved specimens			24
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

OFFICIAL *(Type or Print)*

DATE SIGNED 10/2/03

(AUG 91)

Customer ID and Site Address:

ID: 322

Eaton Hall Biology
Dept.
Geneva, NY 14456
County: Ontario

Telephone
(315)781-3586

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.: 90

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0064
CUSTOMER NUMBER: 182

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Ortho-Clinical Diagnostics, Inc.
Regulatory & Clinical Affairs
1001 U.S. Highway 202
Raritan, NJ 08869

Telephone: (908) -218-8177

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	0	114	233	0	347
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Goats	2	16	3	0	19
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

DATE SIGNED

(AUG 91)

APHIS Form 7023A Site List

The following sites have been reported by the facility:

Registration Number:	22-R-0064
Customer Number:	182
Facility:	Ortho-Clinical Diagnostics, Inc. Regulatory Affairs 1001 U.S. Highway 202 Raritan, NJ 08869 (908) 218-8177

Ortho-Clinical Diagnostics, Inc.
Building K
1001 U.S. Highway 202
Raritan, NJ 08869

Robert Wood Johnson-Pharmaceutical Research Institute
Farming Complex (RWJ-PRI)
County Highway 513
Pittstown, NJ 08868

This re[illegible]s 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[illegible]

See attached form for additional information.

Interagency Report Control No:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0066
CUSTOMER NUMBER: 184

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

University Of Medicine & Dentistry Of Nj
Robert W. Johnson Med. School
675 Hoes Lane
Piscataway, NJ 08854

OCT 24 2003

Telephone: (732) -235-4687

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		4	13		17
5. Cats					
6. Guinea Pigs			2		2
7. Hamsters					
8. Rabbits		32	168		200
9. Non-human Primates					
10. Sheep		3	2		5
11. Pigs			59		59
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		10/22/03

(AUG 91)

Customer ID and Site Address:

ID: 184

UMDNJ-RWJMS
Basic Science Building-Research Tower
675 Hoes Lane, RB01
Piscataway, NJ 08854-5635
County: Middlesex Phone: 732-235-4570

UMDNJ-RWJMS
Medical Education Building
One Robert Wood Johnson Place
New Brunswick, NJ 08901-0019
County: Middlesex Phone: 732-235-7913

UMDNJ-RWJMS
Education and Research Building
401 Haddon Avenue
Camden, NJ 08103
County: Camden Phone: 856-757-9650

University of Medicine and Dentistry of New Jersey
Robert Wood Johnson Medical School

Amendment to Annual Report of Research Facility
Certificate Number: 22-R-0066
Customer Number: 184

Section 3.128 Space Requirements. Enclosures shall be constructed and maintained so as to provide sufficient space to allow each animal to make normal postural and social adjustments with adequate freedom of movement.

Exception: An exception to the standard found in Section 3.128 was requested by the principal investigator based upon scientific necessity and was granted by the IACUC. The explanation is summarized as follows: During observation periods lasting 8 to 12 hours and during a drug infusion period of 48 hours, each pig needs to be confined in a metabolic cage that restricts its horizontal movements. The metabolic cage measures 1.5' wide, 3' long and is 4' high. The pig will be able to stand or recline but will have restricted movement so as not to pull out the pulmonary artery and aortic catheter which would result in exsanguination of the drug infusion catheter. The maximum period of time any individual pig would be confined to the metabolic cage would be 56 hours. The pigs will be transferred to a holding cage with approximately 18 square feet of floor space when they are not being experimentally observed and not being infused.

1/12/04
Date

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

NOV 2 4 2003

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0069
CUSTOMER NUMBER: 185

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Consumer Product Testing Co., Inc.
70 New Dutch Lane
Fairfield, NJ 07004

Telephone: (XXX) 973-808-7111

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	307	3307	0	162	3469
7. Hamsters	1	6	0	0	6
8. Rabbits	15	1392	0	152	1543
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

SIGN

DATE SIGNED
11/21/03

APHIS
(AUG 91)

Consumer Product Testing Co.
EST. 1975

Facility Registration Number: 22-R-0069

The animals listed in Column E of APHIS Form 7023 included 162 guinea pigs and 152 rabbits. The rabbits were used on irritation studies. These studies are used to determine the dermal or ocular irritation potential of the articles tested. The guinea pigs were used on sensitization studies. These studies were used to determine the sensitization potential of the products tested.

In all cases the "procedures producing pain or distress" were either the injection of an adjuvant or the application of an irritating substance to the animal(s) in question. The sponsors of these studies had indicated that the use of anesthetics or analgesics might have interfered with the interpretation of the test results.

As a contract facility, we are not always aware of the nature of the articles being tested and rely upon our sponsors to responsibly determine the appropriateness of the use of anesthetics and/or analgesics.

At the USDA's suggestion, we have included in Column E animals exhibiting maximum irritation scores in the above mentioned study types but not necessarily having exhibited behavioral responses normally associated with pain or distress. In cases where an animal had exhibited a behavioral response normally associated with pain or distress, the response was no more than momentary but the procedure was recorded as "painful" nonetheless.

70 New Dutch Lane • Fairfield, New Jersey 07004-2514 • (973) 808-7111 • Fax (973) 808-7234
Clinical • Toxicology • Analytical Chemistry • Microbiology

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

OCT 0 9 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: 22-R-0076

CUSTOMER NUMBER: 189

FORM APPROVED
OMB NO. 0579-0036

Camden County College
P.O. Box 200
College Drive
Blackwood, NJ 08012
Telephone: (609) 856-227-7200

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of 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	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	8	0	8	0	8
7. Hamsters	0	0	0	0	0
8. Rabbits	12	0	12	0	12
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

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
		10/1/03

(AUG 91)

Customer ID and Site Address:

ID: 189

Animal Science ~~Barn~~ - Truman 129 Telephone (856) 227-7200
Camden County
College
Blackwood, NJ 08012
County: Camden

This report is required by law (7 USC 2143). Failure to report according to the regulations can FEB 0 5 2004 See attached form for additional information

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Amended

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 22-R-0082
CUSTOMER NUMBER: 190

FORM APPROVED
OMB NO. 0579-0036

Product Safety Labs, Inc.
2394 Route 130
Dayton, NJ 08810

Telephone: (732) -438-5100

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		5741		700	6441
7. Hamsters		88			88
8. Rabbits		1387	20	109	1516
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets		187			187

ASSURANCE STATEMENTS

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

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

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

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

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

DATE SIGNED 2/3/04

APHIS FORM 7023
(AUG 91)

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

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

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: 22-R-0082

CUSTOMER NUMBER: 190

FORM APPROVED
OMB NO. 0579-0036

Product Safety Labs, Inc.
2394 Route 130
Dayton, NJ 08810

Telephone: (732) -438-5100

NOV 20 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	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					
5. Cats					
6. Guinea Pigs		5741			6441
7. Hamsters		88			88
8. Rabbits		1387	20	109	1516
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets		187			187

ASSURANCE STATEMENTS

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

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

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

DATE SIGNED 11/19/03

APHIS FORM 7023 (AUG 91)

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

Registration Number: 22-R-0082

ATTACHMENT TO USDA/APHIS ANNUAL REPORT OF RESEARCH FACILITY

EXPLANATION OF COLUMN "E" ENTRIES

10/01/02 through 9/30/03

102 Rabbits – Eye Irritation Test (OPPTS 870.2400): Thirteen (13) of these animals vocalized following instillation of the test compound but immediately became calm after they were returned to their cage. Therefore, anesthetic was not considered. Although the remaining animals (89) did not exhibit overt signs of pain or distress, they exhibited ocular irritation scores above an arbitrary threshold and were considered to be in distress as a result of their exposure to the test compound. Although in the eye irritation test ocular anesthetic may be used prior to instillation, repeated and/or prolonged anesthetic use could retard healing and possibly lead to collateral irritation and/or subsequent corneal infection. Therefore, ocular anesthetic was not used on the animals evidencing ocular irritation scores above this established threshold limit.

7 Rabbits – Dermal Irritation Test (OPPTS 870.2500): All animals exhibited eschar and/or corrosion at the dose site, which could indicate possible necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was ≤ 1 in^2. Continuous or prolonged use of topical or systemic anesthetic agents during dermal irritation tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of irritation. If used, they might significantly alter the effects of the test compound and compromise study results.

700 Guinea Pigs – Dermal Sensitization Test (OPPTS 870.2600): Similar to the dermal irritation test noted above, these animals exhibited eschar and/or corrosion at the dose site, which could indicate possible necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was ≤ 1 in^2. Continuous or prolonged use of topical or systemic anesthetic agents during dermal sensitization tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of sensitization. If used, they might significantly alter the effects of the test compound and compromise study results.

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

DEC 0 1 2003

See attached form for additional information.

Interagency Report Control No.: PSM

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 22-R-0099

CUSTOMER NUMBER: 194

FORM APPROVED
OMB NO. 0579-0036

University Of Medicine & Dentistry Of Nj
School Of Osteopathic Medicine
2 Medical Center Drive
Stratford, NJ 08084

Telephone: (856) -566-6119

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
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 11/25/03

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

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21! DEC 0 2 2003 See attached form for additional information. Interagency Report Control No.: R8M

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 22-R-0104
CUSTOMER NUMBER: 198

FORM APPROVED
OMB NO. 0579-0036

Center For Molecular Med & Immunology
520 Bellville Ave
Belleville, NJ 07109

Telephone: (973) -844-7000

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 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					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice		168	7523		7691
Rats			24		24

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 C... | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) | DATE SIGNED 11/26/03

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

DEC 01 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: 22-R-0116
CUSTOMER NUMBER: 695

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Xenobiotic Laboratories, Inc.
107 Morgan Lane
Plainsboro, NJ 08536

Telephone: (609) -799-2295

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	16	0	1	17
5. Cats		0		0	0
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

SIGNATI

or Print)

DATE SIGNED 11-25-03

APHIS FC
(AU

799

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: 22-R-0116

2. Number 1 (not on study) of animals used in this study.

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

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

Dog accidentally got neck/head stuck in chain provided to aid in cleaning process. Dog struggled causing strangulation + death. Dog was not on study

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

None. Not on study. Accidental death. All chains immediately removed + USDA + vet notified.

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

Agency_____ CFR_____

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

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0117
CUSTOMER NUMBER: 701

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Barton'S West End Farms, Inc.
161 Janes Chapel Road
Oxford, NJ 07863

Telephone: (908) -637-4427

NOV 25 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 necessarv or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	219	26	0	245
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	12	0	0	12
9. Non-human Primates	7	0	0	0	0
10. Sheep	0	0	1	0	1
11. Pigs	2	0	47	0	47
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

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

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

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

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

DATE SIGNED
24-NOV-0

Customer ID and Site Address:

ID: 701

Po Box 290
Lakewood, NJ 18430 0290
County: Ocean

Telephone

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: 22-R-0118
CUSTOMER NUMBER: 1672

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Pediatric Cardiology
137 Pavalion Avenue
Long Branch, NJ 07740

OCT 07 2003

Telephone: (908) -870-1611

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			Not used. will start soon.		
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

SIGNATURE OF C

DATE SIGNED 9/30/03

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

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 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: 22-R-0123
CUSTOMER NUMBER: 1824

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

County College Of Morris
Veterinary Tech. Program
214 Center Grove Road
Randolph, NJ 07869

OCT 0 2 2003

Telephone: (973) -328-5340

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	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	4	0	0	4
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual 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
		9/25/03

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: 22-R-0125
CUSTOMER NUMBER: 11697

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Hackensack University Medical Center
Institute For Biomedical Research
David Joseph Jurist Research Bldg
30 Prospect Ave
Hackensack, NJ 07601

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			9		
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			5		
9. Non-human Primates					
10. Sheep					
11. Pigs	1		45		
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

DATE SIGNED
10-09-03

A

Customer ID and Site Address:

ID: 11697

Institute For
Biomedical Research
Hackensack, NJ 07601
County: Bergen

Telephone
(201)996-2879

DEC 0 2 2003

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

See attached form for additional information.

Interagency Report Control No.: RSM

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0130
CUSTOMER NUMBER: 1701

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Qualtech Laboratories, Inc.
104 Green Grove Road
Ocean, NJ 07712

Telephone: ~~(908)~~ 732 -918-0207

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use 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	0	0	0	0
5. Cats	0	0	3	0	3
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

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

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

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

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

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

S

DATE SIGNED 11-28-03

AF

(AUG 91)

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

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0131
CUSTOMER NUMBER: 16333

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Kraft Foods North America, Inc
Sherburne Pet Food Testing Center
200 De Forest Avenue
East Hanover, NJ 07936

Telephone: (607) -674-9414

NOV 21 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	180	118	0	0	118
5. Cats	0	051	0	0	51
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

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

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

SIGNATURE OF C.E.O.

DATE SIGNED 10/30/03

APHIS FORM 7023 (AUG 91)

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

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

SEP 2 3 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: 22-R-0132
CUSTOMER NUMBER: 188

FORM APPROVED
OMB NO. 0579-0036

Gibraltar Laboratories, Inc.
122 Fairfield Road
Fairfield, NJ 07004

Telephone: (973) -227-6882

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

FACILITY LOCATIONS (Sites) - See Atached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	~~0~~ 0	~~0~~ 6	~~0~~ 0	0	6
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals (Mice)	100	100	0	0	100
	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)

SIGI

(Type or Print)

DATE SIGNED 9/19/03

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

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

OCT 29 2003 See attached form for additional information.

Interagency Report Control No.: Star

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0133
CUSTOMER NUMBER: 406

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Public Health Research Institute
225 Warren Street
Newark, NJ 07103

Telephone: (973) -972-9150 (no longer in use)
New Telephone No. 973-854-3100

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	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	1	44	0	45
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

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

or Print)

DATE SIGNED 10/28/03

APHIS FORM 7023
(AUG 91)

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

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0134
CUSTOMER NUMBER: 183

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

William Paterson University Of New Jersey
Department Of Biology
300 Pompton Road
Wayne, NJ 07470

Telephone: (973) -720-3440

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)

SCIENCE HALL ROOMS 206-208 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 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					0
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					0
		ONLY LABORATORY MICE AND RATS			
		WERE HOUSED HERE THIS YEAR			

ASSURANCE STATEMENTS

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

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

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

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

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

SIGN[illegible] | [illegible] | DATE SIGNED

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

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: 22-R-0135
CUSTOMER NUMBER: 22320

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Transave Inc
11 Deer Park Drive Suite 117
Monmouth Junction, NJ 08852 OCT 24 2003

Telephone: (732) -438-9434

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

ASSURANCE STATEMENTS

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

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

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

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

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

rint)

DATE SIGNED 10/20/03

Customer ID and Site Address:

ID: 22320

11 Deer Park Drive
Suite 117
Monmouth Junction, NJ 08852 1923
County: Middlesex

Telephone 732-438-9434 Ext 35

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.