# Annual Report of Research Facility

**2003 U.S. Department of Agriculture**

**Animal and Plant Health Inspection Service**

**ANNUAL REPORT OF RESEARCH FACILITY**

**(Type or Print)**

<table>
<thead>
<tr>
<th>1. CERTIFICATE NUMBER: 22-R-0001</th>
<th>CUSTOMER NUMBER: 158</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell Labs Lucent Technologies</td>
<td>600 Mountain Avenue</td>
</tr>
<tr>
<td>P. O. Box 536</td>
<td>Murray Hill, NJ 07974</td>
</tr>
<tr>
<td>Telephone: (908) -582-5696</td>
<td></td>
</tr>
</tbody>
</table>

## Reporting Facility

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

###Facility Locations (Sites)

See Attached Listing

###Report of Animals Used by or Under Control of Research Facility

(Attach additional sheets if necessary or use APHIS Form 7023A)

<table>
<thead>
<tr>
<th>Number of animals</th>
<th>Number of animals</th>
<th>Number of animals</th>
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<tbody>
<tr>
<td>being bred,</td>
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<tr>
<td>conditioned, or</td>
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<td>or tests were</td>
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<tr>
<td>or tests were</td>
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<td>to the animals</td>
<td>to the animals</td>
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<td>were</td>
<td>for which</td>
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<td></td>
<td>or tranquilizing</td>
<td>or tranquilizing</td>
<td>or tranquilizing</td>
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<tr>
<td></td>
<td>drugs used.</td>
<td>drugs used.</td>
<td>drugs used.</td>
<td>drugs used.</td>
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</tbody>
</table>

###Assurance Statements

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

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

3. This facility is adhering to the standards and regulations under the Act, and it has been determined that exceptions to the standards and regulations be specified and explained by the principal investigator and 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 in brief explanation of the exceptions, as well as the number of animals affected.

4. The attending veterinarian for this research facility has appropriate 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**

**Date Signed**

1/20/03

**APHIS Form 7023**

(AUG 91)
### Annual Report of Research Facility

**Type or Print**

**LAB BLDG. - PH+F+L**

**FACILITY LOCATIONS (Sites)** - See Attached Listing

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

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

### Assurance Statements

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

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

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

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

### Certification by Headquarters Research Facility Official

(Chief Executive Officer or Legally Responsible Institutional Official)

**DATE SIGNED**

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

(AUG 91)
**UNITED STATES DEPARTMENT OF AGRICULTURE**
**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**ANNUAL REPORT OF RESEARCH FACILITY**
(TYPE OR PRINT)

<table>
<thead>
<tr>
<th>A.</th>
<th>B.</th>
<th>C.</th>
<th>D.</th>
<th>E.</th>
<th>F.</th>
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<tbody>
<tr>
<td>4. Dogs</td>
<td>50</td>
<td>370*</td>
<td>197*</td>
<td>34*</td>
<td>601</td>
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<tr>
<td>5. Cats</td>
<td>-</td>
<td>-</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>6. Guinea Pigs</td>
<td>12</td>
<td>729*</td>
<td>795*</td>
<td>30</td>
<td>1554</td>
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<tr>
<td>7. Hamsters</td>
<td>20</td>
<td>0</td>
<td>661*</td>
<td>446</td>
<td>1107</td>
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<tr>
<td>8. Rabbits</td>
<td>5*</td>
<td>0</td>
<td>183*</td>
<td>0</td>
<td>183</td>
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<td>9. Non-human Primates</td>
<td>14*</td>
<td>16*</td>
<td>52*</td>
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<td>-</td>
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<td>-</td>
</tr>
<tr>
<td>11. Pigs</td>
<td>-</td>
<td>-</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>12. Other Farm Animals</td>
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<td>-</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>13. Other Animals</td>
<td>-</td>
<td>-</td>
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</tr>
</tbody>
</table>

**ASSURANCE STATEMENTS**

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

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

3. The facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and 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 assure 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
**USDA ANNUAL REPORT (2002-2003)**

**Registration #: 22-R-0006**

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

<table>
<thead>
<tr>
<th>SPECIES</th>
<th>CATEGORY B</th>
<th>CATEGORY C</th>
<th>CATEGORY D</th>
<th>CATEGORY E</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOGS</td>
<td>0</td>
<td>170</td>
<td>154</td>
<td>18</td>
</tr>
<tr>
<td>GUINEA PIGS</td>
<td>0</td>
<td>8</td>
<td>141</td>
<td>0</td>
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<tr>
<td>HAMSTERS</td>
<td>0</td>
<td>0</td>
<td>122</td>
<td>0</td>
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<td>RABBITS</td>
<td>5</td>
<td>0</td>
<td>53</td>
<td>0</td>
</tr>
<tr>
<td>NON-HUMAN PRIMATES</td>
<td>12</td>
<td>11</td>
<td>52</td>
<td>0</td>
</tr>
</tbody>
</table>
**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:

<table>
<thead>
<tr>
<th>SPECIES</th>
<th>NUMBER</th>
<th>PROCEDURE/JUSTIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
<td>34</td>
<td>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</td>
</tr>
<tr>
<td>Guinea Pigs</td>
<td>30</td>
<td>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</td>
</tr>
<tr>
<td>Hamster</td>
<td>446</td>
<td>Studies are used for evaluating anti-inflammatory compounds. Dorsal sub-cutaneous air pouch and paw edema models are utilized. 1</td>
</tr>
</tbody>
</table>

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).
### ANNUAL REPORT OF RESEARCH FACILITY

**TYPE OR PRINT**

**FACILITY LOCATIONS (Sites)** - See Attached Listing

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

<table>
<thead>
<tr>
<th>Animals Covered by The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
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<th>E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)</th>
<th>F. TOTAL NUMBER OF ANIMALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
<td>42</td>
<td>424</td>
<td>41</td>
<td>92</td>
<td>557</td>
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<tr>
<td>Cats</td>
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<td></td>
</tr>
<tr>
<td>Guinea Pigs</td>
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<tr>
<td>Hamsters</td>
<td>876</td>
<td>7</td>
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<td>883</td>
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<tr>
<td>Rabbits</td>
<td>9</td>
<td>522</td>
<td>52</td>
<td>47</td>
<td>621</td>
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<tr>
<td>Non-human Primates</td>
<td>210</td>
<td>344</td>
<td>69</td>
<td>52</td>
<td>465</td>
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<tr>
<td>Sheep</td>
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<tr>
<td>Pigs</td>
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<tr>
<td>Other Farm Animals</td>
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<tr>
<td>Other Animals</td>
<td></td>
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</tr>
</tbody>
</table>

#### ASSURANCE STATEMENTS

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

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

3. This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and to 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 an explanation of the exceptions, as well as the species and number of animals affected.

4. The attending veterinarian for this research facility has appropriate 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 Designee/Responsible Institutional Official)

DATE SIGNED: 11-26-93
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)
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)
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)
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 (52 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)
OPTONAL 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)
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:

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:

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:

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:

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:

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:


   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:


   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:


   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:


   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:


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:


2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).
Summary of the NACUC approved exceptions to the Standards and Regulations:
Canine Exercise Exemptions

<table>
<thead>
<tr>
<th>Protocol Title</th>
<th>Species</th>
<th>Number</th>
<th>Days Without Exercise</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>1. Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog</td>
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<td>7</td>
<td>Quantitative collection of excreta, containment of radioactivity</td>
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<td>Quantitative collection of excreta, containment of radioactivity</td>
</tr>
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<td>3. Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog</td>
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<td>02</td>
<td>9</td>
<td>Quantitative collection of excreta, containment of radioactivity</td>
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<td>4. Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog</td>
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<td>15</td>
<td>Treatment of Giardia</td>
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<tr>
<td>5. Absorption, Metabolism and Excretion After A Single Oral or IV Dose in the Dog</td>
<td>Dogs</td>
<td>01</td>
<td>30</td>
<td>Possible Transmissible Infection</td>
</tr>
<tr>
<td>6. Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies</td>
<td>Dogs</td>
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<td>14</td>
<td>Surgical recovery of dogs implanted with telemetry devices</td>
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<tr>
<td>Protocol Title</td>
<td>Species</td>
<td>Number</td>
<td>Exercise</td>
<td>Reason</td>
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<tr>
<td>Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies</td>
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<td>12</td>
<td>Surgical recovery of dogs implanted with telemetry devices</td>
</tr>
<tr>
<td>Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies</td>
<td>Dogs</td>
<td>7</td>
<td>10</td>
<td>Surgical recovery of dogs implanted with telemetry devices</td>
</tr>
<tr>
<td>Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys Intended for Use on Safety Pharmacology Studies</td>
<td>Dogs</td>
<td>1</td>
<td>13</td>
<td>Surgical recovery of dogs implanted with telemetry devices</td>
</tr>
</tbody>
</table>
# Annual Report of Research Facility

## Facility Locations

### 1. Certificate Number: 22-R-0013

#### Customer Number: 163

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 Attached Listing

## Report of Animals Used by or Under Control of Research Facility

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, surgery or other use not yet used for such purposes.</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>E. Number of animals upon which teaching, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)</th>
<th>F. Total Number of Animals (Columns C + D + E)</th>
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</thead>
<tbody>
<tr>
<td>4. Dogs</td>
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<td>6. Guinea Pigs</td>
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<td>7. Hamsters</td>
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<td>8. Rabbits</td>
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<tr>
<td>9. Non-human Primates</td>
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<td>11. Pigs</td>
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<td>12. Other Farm Animals</td>
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<td>13. Other Animals</td>
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</tr>
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</table>

### Assurance Statements

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

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

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

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

## Certification by Headquarters Research Facility Official

(Chief Executive Officer or Legally Responsible Institutional Official)

Date Signed: 11/24/93

(AJS 91)
# ANNUAL REPORT OF RESEARCH FACILITY

**TYPE OR PRINT**

1. **CERTIFICATE NUMBER:** 22-R-0016  
   **CUSTOMER NUMBER:** 174

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 Attached Listing

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

- **COLUMNS C + D + E**

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.</th>
<th>D. Number of animals upon which teaching, research, experiments, or tests were conducted involving pain or distress to the animals.</th>
<th>E. Number of animals upon which teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>F. TOTAL NUMBER OF ANIMALS</th>
</tr>
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<tbody>
<tr>
<td>Dogs</td>
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<td>Cats</td>
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<td>Hamsters</td>
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<td>Rabbits</td>
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<td>Pigs</td>
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<td>Other Animals</td>
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</tr>
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## ASSURANCE STATEMENTS

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

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

3. This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and 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 an explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached this report.

4. The attending veterinarians for this research facility have appropriate 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**

(AUG 91)
### ANNUAL REPORT OF RESEARCH FACILITY

**TYPE OR PRINT**

**FACILITY LOCATIONS (Sites) - See Attached Listing**

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

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not used for such purposes.</th>
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<th>E. Number of animals upon which teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)</th>
<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
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<td>13. Other Animals</td>
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</tbody>
</table>

**Woodchucks**

**23**

**TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)**

**ASSURANCE STATEMENTS**

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

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

3. This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and to 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 to 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**

**DATE SIGNED**

(AUG 91)
### ANNUAL REPORT OF RESEARCH FACILITY

**TYPE OR PRINT**

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

Princeton University  
Office Of Research & Projects  
P.O. Box 36  
Princeton, NJ 08544  
Telephone: (609) -258-3090

### FACILITY LOCATIONS

*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.*

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

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals for which appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
<th>E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)</th>
<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
</tr>
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### ASSURANCE STATEMENTS

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

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

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and 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 brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility 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: 11/25/03*
### ANNUAL REPORT OF RESEARCH FACILITY

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

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

**Rutgers-State University Of Nj**  
Research & Sponsored Programs  
3 Rutgers Plaza  
New Brunswick, NJ 08901  
Telephone: (732) -932-0150

**DEC 05 2003**

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

**Interagency Report Control No.**

**FORM APPROVED**  
OMB NO. 0579-0036

---

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

**FACILITY LOCATIONS (Sites)** - See Attached Listing

---

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

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, research, experiments, or surgery (not used for such purposes).</th>
<th>C. Number of animals upon which teaching, research, or experiments were conducted involving no pain, distress, or use of pain-relieving drugs.</th>
<th>D. Number of animals upon which teaching, research, or experiments were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>E. Number of animals upon which teaching, research, or experiments were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td>16</td>
<td>58</td>
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<td>5. Cats</td>
<td>27</td>
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<td></td>
<td>27</td>
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<tr>
<td>6. Guinea Pigs</td>
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<td></td>
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<td></td>
<td>5</td>
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<tr>
<td>10. Sheep</td>
<td></td>
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<td></td>
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<tr>
<td>11. Pigs</td>
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<tr>
<td>12. Other Farm Animals</td>
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</tr>
</tbody>
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---

**ASSURANCE STATEMENTS**

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

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

---

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**

(Chief Executive Officer or Legally Responsible Institutional Official)

---

**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
Customer ID and Site Address:

ID: 177
P.O. Box 1059
Bldg 7002 Science
Camden, NJ 08101
County: Camden
Customer ID and Site Address:

ID: 177
Psarf Complex &
Bartlett Hall
New Brunswick, NJ 08901
County: Middlesex
Customer ID and Site Address:

ID: 177
197 University Avenue
Newark, NJ 07102
County: Essex
### UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**ANNUAL REPORT OF RESEARCH FACILITY**
(TYPE OR PRINT)

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs</th>
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<th>E. Number of animals upon which teaching, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
<td>3</td>
<td>749</td>
<td>1061</td>
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<td>Cats</td>
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<td>Guinea Pigs</td>
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<td>2288</td>
<td>467</td>
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<td>2440</td>
<td>873</td>
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<td>3379</td>
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<tr>
<td>Non-human Primates</td>
<td>3778</td>
<td>188</td>
<td>877</td>
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<tr>
<td>Sheep</td>
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<tr>
<td>Pigs</td>
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<tr>
<td>Other Farm Animals</td>
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</tr>
<tr>
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<td>Gerbils</td>
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<td>32</td>
<td>32</td>
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</tr>
</tbody>
</table>

### ASSURANCE STATEMENTS

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

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

[Signature]

[Date: 11/22/13]
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.
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.
### UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**ANNUAL REPORT OF RESEARCH FACILITY**
*(TYPE OR PRINT)*

<table>
<thead>
<tr>
<th>1. CERTIFICATE NUMBER:</th>
<th>22-R-0031</th>
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</thead>
<tbody>
<tr>
<td>CUSTOMER NUMBER:</td>
<td>179</td>
</tr>
</tbody>
</table>

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 Attached Listing

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

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<tr>
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<th>E. Number of animals upon which teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which 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 this report.)</th>
<th>F. TOTAL NUMBER OF ANIMALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td>7</td>
<td>52</td>
<td></td>
<td></td>
<td>52</td>
</tr>
<tr>
<td>5. Cats</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6. Guinea Pigs</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>7. Hamsters</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>8. Rabbits</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Non-human Primates</td>
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<tr>
<td>10. Sheep</td>
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<td>12. Other Farm Animals</td>
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</tr>
<tr>
<td>13. Other Animals</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

**ASSURANCE STATEMENTS**

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

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

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

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

**DATE SIGNED:**

(2) 24/03

(AUG 91)
## ANNUAL REPORT OF RESEARCH FACILITY

**TYPE OR PRINT**

### REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

(Attach additional sheets if necessary or use APHIS Form 7023A)

<table>
<thead>
<tr>
<th></th>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
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<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
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</thead>
<tbody>
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<td>4. Dogs</td>
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<td>0</td>
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</tr>
<tr>
<td>8. Guinea Pigs</td>
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<td>10</td>
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<td>15</td>
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</tr>
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</tr>
<tr>
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<td>9. Non-human Primates</td>
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<td>10. Sheep</td>
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<td>0</td>
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</tr>
</tbody>
</table>

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### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

**SIGNATURE**

**DATE SIGNED**

**November 28, 2003**

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

**AUG 91**
Column E Explanation

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

1. Registration Number: 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 _____________________________
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
   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 yet

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   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
spiny mice 275

ASSURANCE STATEMENTS

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

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

SIGI

DATE SIGNED 12/1/03

APHIL (AUG 91)
# ANNUAL REPORT OF RESEARCH FACILITY

## Facility Information

**UNIVERSITY OF AGRICULTURE**

**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**ANNUAL REPORT OF RESEARCH FACILITY**

**CERTIFICATE NUMBER:** 22-R-0038

**CUSTOMER NUMBER:** 677

**Bracco Research Usa, Inc.**

305 College Road East
Princeton, NJ 08540

Telephone: (609) -514-2524 or .240

### 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**

(See Attached Listing)

Same address as above.

### REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

<table>
<thead>
<tr>
<th>A. Animals Covered</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.</th>
<th>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 the use of appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>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.</th>
<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td>0</td>
<td>0</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5. Cats</td>
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<td>0</td>
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<td>0</td>
</tr>
<tr>
<td>6. Guinea Pigs</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>7. Hamsters</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>8. Rabbits</td>
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<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>9. Non-human Primates</td>
<td>0</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10. Sheep</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>11. Pigs</td>
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<tr>
<td>12. Other Farm Animals</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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 anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.

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

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

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

### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

**DATE SIGNED**

DEC 10 2003

(Republic vs POLAK 18-23 [UCC 68], which is obsolete)

[AUG 91]
ANNUAL REPORT OF RESEARCH FACILITY

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

FACILITY LOCATIONS (Sites) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations

B. Number of animals being bred, conditioned, or held for use in teaching, research, experiments, research, or surgery but not yet used for such purposes.

C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.

D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals 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 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 this report.)

F. TOTAL NUMBER OF ANIMALS

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<thead>
<tr>
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<td>180</td>
<td>128</td>
<td>9</td>
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<td>C</td>
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</tr>
</tbody>
</table>

ASSURANCE STATEMENTS

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

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

DATE SIGNED

1/9/03

STAMP
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
- 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 Huntington 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.

<table>
<thead>
<tr>
<th>Species</th>
<th>Number of Category E Animals</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbits</td>
<td>7</td>
<td>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.</td>
</tr>
<tr>
<td>Dogs</td>
<td>5</td>
<td>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.</td>
</tr>
<tr>
<td>Dogs</td>
<td>2</td>
<td>Animals were exposed to test compound via intravenous administration once. Test article effects were evident in 2 animals. Dose was discontiuued in both affected animals.</td>
</tr>
<tr>
<td>Dogs</td>
<td>2</td>
<td>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.</td>
</tr>
<tr>
<td>Primate</td>
<td>8</td>
<td>Animals were exposed to test compound via intravenous administration for 8 days. Test article effects of brief duration resolved spontaneously in 8 affected animals.</td>
</tr>
<tr>
<td>Primate</td>
<td>1</td>
<td>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.</td>
</tr>
<tr>
<td>Species</td>
<td>Number of Category E Animals</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Primate</td>
<td>10</td>
<td>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.</td>
</tr>
<tr>
<td>Primate</td>
<td>7</td>
<td>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.</td>
</tr>
<tr>
<td>Primate</td>
<td>2</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.
### UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

### ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

<table>
<thead>
<tr>
<th>1. CERTIFICATE NUMBER: 22-R-0041</th>
</tr>
</thead>
<tbody>
<tr>
<td>CUSTOMER NUMBER: 173</td>
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</tbody>
</table>

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

Telephone: (201) -847-6800

### FACILITY LOCATIONS (Sites - See Attached Listing)

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

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs</th>
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<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td>0</td>
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<tr>
<td>5. Cats</td>
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<tr>
<td>6. Guinea Pigs</td>
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<tr>
<td>7. Hamsters</td>
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<tr>
<td>8. Rabbits</td>
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<td>18</td>
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<tr>
<td>9. Non-human Primates</td>
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<tr>
<td>10. Sheep</td>
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<tr>
<td>11. Pigs</td>
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<td></td>
<td>579</td>
</tr>
<tr>
<td>12. Other Farm Animals</td>
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<td></td>
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<td></td>
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<tr>
<td>13. Other Animals</td>
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<td></td>
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<td>0</td>
</tr>
</tbody>
</table>

#### ASSURANCE STATEMENTS

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

[Signature]

3 Oct. 03
Customer ID and Site Address:

ID: 173
21 Davis Drive
Research Triangle Pa, NC  27709
County: Durham

Telephone
(919)597-6151
**UNITED STATES DEPARTMENT OF AGRICULTURE**  
**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

| 1. CERTIFICATE NUMBER: 21-R-0061 | FORM APPROVED  
| CUSTOMER NUMBER: 322 | OMB NO. 0579-0036 |

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

Telephone: (315) -781-3586

### FACILITY LOCATIONS (Sites) - See Attached Listing

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

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being housed, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
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<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td>24 preserved specimens</td>
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<tr>
<td>5. Cats</td>
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<td></td>
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<tr>
<td>6. Guinea Pigs</td>
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<td>7. Hamsters</td>
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<tr>
<td>8. Rabbits</td>
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<tr>
<td>9. Non-human Primates</td>
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<tr>
<td>10. Sheep</td>
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<tr>
<td>11. Pigs</td>
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<tr>
<td>12. Other Farm Animals</td>
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<tr>
<td>13. Other Animals</td>
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</tr>
</tbody>
</table>

### ASSURANCE STATEMENTS

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**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
### ANNUAL REPORT OF RESEARCH FACILITY

**TYPE OR PRINT**

<table>
<thead>
<tr>
<th>1. CERTIFICATE NUMBER:</th>
<th>22-R-0064</th>
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<tbody>
<tr>
<td>2. CUSTOMER NUMBER:</td>
<td>182</td>
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</tbody>
</table>

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 Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY**
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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
<td></td>
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<td>5. Cats</td>
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<td>6. Guinea Pigs</td>
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<td>11. Pigs</td>
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</tbody>
</table>

**ASSURANCE STATEMENTS**

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

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

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

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

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**

(Chief Executive Officer or Legally Responsible Institutional Official)

**DATE SIGNED**
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
**UNITED STATES DEPARTMENT OF AGRICULTURE**  
**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**ANNUAL REPORT OF RESEARCH FACILITY**  
(*TYPE OR PRINT*)

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</thead>
<tbody>
<tr>
<td>CUSTOMER NUMBER:</td>
<td>184</td>
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</tbody>
</table>

University Of Medicine & Dentistry Of Nj  
Robert W. Johnson Med. School  
675 Hoos Lane  
Piscataway, NJ 08854  
Telephone: (732) -235-4687

**OCT 24 2003**

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

| FACILITY LOCATIONS (Sites) | See Attached Listing |

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

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals for which appropriate anesthetic, analgesic, or tranquilizing drugs were used</th>
<th>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 tranquilizer drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)</th>
<th>F. TOTAL NUMBER OF ANIMALS (COLUMN C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>9. Non-human Primates</td>
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<td>11. Pigs</td>
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<td>12. Other Farm Animals</td>
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<td>59</td>
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</tbody>
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**ASSURANCE STATEMENTS**

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

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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**

(Chief Executive Officer or Legally Responsible Institutional Official)

<table>
<thead>
<tr>
<th>DATE SIGNED</th>
<th>10/21/03</th>
</tr>
</thead>
</table>
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
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
**United States Department of Agriculture**
**Animal and Plant Health Inspection Service**

**Annual Report of Research Facility**
(Type or Print)

<table>
<thead>
<tr>
<th>1. Certificate Number: 22-R-0069</th>
<th>Form Approved OMB No. 0579-0036</th>
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<tr>
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Consumer Product Testing Co., Inc.
70 New Dutch Lane
Fairfield, NJ 07004
Telephone: (201) -808-7111 973

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

FACILITY LOCATIONS (Sites) - See Attached Listing

**Report of Animals Used by or Under Control of Research Facility**
(Attach additional sheets if necessary or use APHIS Form 7023A)

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.</th>
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<th>D. Number of animals upon which teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals or for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
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<th>F. Total number of animals (Columns C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
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<td>5. Cats</td>
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<tr>
<td>10. Sheep</td>
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<td>11. Pigs</td>
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<td>13. Other Animals</td>
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</tbody>
</table>

**Assurance Statements**

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**Certification by Headquarters Research Facility Official**
(Chief Executive Officer or Legally Responsible Institutional Official)

Sign: [Signature]
Date Signed: 11/21/03
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.
# ANNUAL REPORT OF RESEARCH FACILITY

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

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

**CERTIFICATE NUMBER:** 22-R-0076  
**CUSTOMER NUMBER:** 189

1. **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)

2. **FACILITY LOCATIONS** (Sites) - See Attached Listing

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<thead>
<tr>
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<th>F. TOTAL NUMBER OF ANIMALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
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<td>5. Cats</td>
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<tr>
<td>6. Guinea Pigs</td>
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<td>8. Rabbits</td>
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### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

**SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL:**  
**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL:** (Type or Print)  
**DATE SIGNED:** [10/1/83]

( AUG 91 )
Customer ID and Site Address:

ID: 189
Animal Science Barn - Truman 12A  Telephone (856) 227-7200
Camden County
College
Blackwood, NJ  08012
County: Camden
**Amended**  
ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

<table>
<thead>
<tr>
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<th>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</th>
<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C+D+E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
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**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 86), which is obsolete.)
ANNUAL REPORT OF RESEARCH FACILITY

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FACILITY LOCATIONS (Sites) - See Attached Listing

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

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<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Animals</th>
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<tbody>
<tr>
<td>Dogs</td>
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<td>Rabbits</td>
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<tr>
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<td>Pigs</td>
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<td>Other Farm Animals</td>
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<td>Total</td>
<td>6441</td>
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ASSURANCE STATEMENTS

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

Signed: [Signature]

DATE SIGNED: 11/19/03

NOTICE: This form replaces V5 Form 18-23 (OCT 88), which is obsolete.
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 in². 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 in². 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.
### ANNUAL REPORT OF RESEARCH FACILITY

**TYPE OR PRINT**

<table>
<thead>
<tr>
<th>A. Animals Covered by the Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.</th>
<th>D. Number of animals upon which teaching, research, experiments, or tests were conducted involving accompanying pain or distress to the animals or for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>E. Number of animals upon which teaching, research, experiments, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)</th>
<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
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<td>5. Cats</td>
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</table>

### ASSURANCE STATEMENTS

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

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

3. This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and 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 an explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used.

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

### CERTIFICATION

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNED

DATE SIGNED: 11/25/03

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

(AUG 91)
### ANNUAL REPORT OF RESEARCH FACILITY

**TYPE OR PRINT**

<table>
<thead>
<tr>
<th><strong>1. CERTIFICATE NUMBER:</strong></th>
<th>22-R-0104</th>
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<tbody>
<tr>
<td><strong>CUSTOMER NUMBER:</strong></td>
<td>198</td>
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</tbody>
</table>

Center For Molecular Med & Immunology  
520 Belleville 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

See Attached Listing

### REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

(Attach additional sheets if necessary or use APHIS Form 7023A)

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
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<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
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<tbody>
<tr>
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<tr>
<td>Guinea Pigs</td>
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<tr>
<td>Hamsters</td>
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<td>Non-human Primates</td>
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<tr>
<td>Sheep</td>
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<tr>
<td>Pigs</td>
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<tr>
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### ASSURANCE STATEMENTS

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

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

### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

**SIGNATURE**  
**DATE SIGNED**  

<table>
<thead>
<tr>
<th>SIGNATURE (REPLACES V.S. FORM 18-23 (OCT 88), WHICH IS OBSOLETE.)</th>
<th>DATE SIGNED</th>
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<tbody>
<tr>
<td>(AUG 91)</td>
<td>11/26/03</td>
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APHIS FORM 7023
### FACILITY LOCATIONS

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.)

### REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.</th>
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<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
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<tr>
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<td>0</td>
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</tr>
</tbody>
</table>

### ASSURANCE STATEMENTS

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### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

<table>
<thead>
<tr>
<th>SIGNATURE</th>
<th>DATE SIGNED</th>
</tr>
</thead>
<tbody>
<tr>
<td>APHIS FC</td>
<td>11-25-03</td>
</tr>
</tbody>
</table>
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-C1116

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 __________________________
**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

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

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<thead>
<tr>
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<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
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<td>13. Other Animals</td>
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</tr>
</tbody>
</table>

**ASSURANCE STATEMENTS**

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

**DATE SIGNED**

[Signature]
Customer ID and Site Address:

ID: 701
Po Box 290
Lakewood, NJ 08704-2900
County: Ocean
# Annual Report of Research Facility

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

## Annual Report of Research Facility

**TYPE OR PRINT**

1. **Certificate Number:** 22-R-0118  
2. **Customer Number:** 1672  
3. **Facility:** Pediatric Cardiology  
   137 Pavillon Avenue  
   Long Branch, NJ 07740  
   Telephone: (908) -870-1611  

### 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

See attached listing

### Report of Animals Used by or Under Control of Research Facility

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
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<th>F. Total Number of Animals (Columns C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>10. Sheep</td>
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<tr>
<td>11. Pigs</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Assurance Statements

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### Certification by Headquarters Research Facility Official

(Chief Executive Officer or Legally Responsible Institutional Official)

**Signature of C.**

**Date Signed:** 9/30/22

**APHIS Form 7023** (Replaces VS Form 18-23 (OCT 88), which is obsolete)

(AUG 91)
### FACILITY LOCATIONS (Sites) - See Attached Listing

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

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<thead>
<tr>
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<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>13. Other Animals</td>
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</tbody>
</table>

**ASSURANCE STATEMENTS**

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

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

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

<table>
<thead>
<tr>
<th>SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL</th>
<th>NAME &amp; TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL</th>
<th>DATE SIGNED</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Signature)</td>
<td>(Name and Title)</td>
<td>9/25/03</td>
</tr>
</tbody>
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### ANNUAL REPORT OF RESEARCH FACILITY

**UNIVERSITY OF NEW JERSEY**

**Institute For Biomedical Research**

David Joseph Jurist Research Bldg

30 Prospect Ave

Hackensack, NJ 07601

---

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY**

**A. Animals Covered by the Animal Welfare Regulations**

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
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<td>Cats</td>
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<td></td>
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<tr>
<td>Guinea Pigs</td>
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<tr>
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<tr>
<td>Non-human Primates</td>
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<td>Pigs</td>
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<tr>
<td>Other Animals</td>
<td></td>
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</tr>
</tbody>
</table>

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### ASSURANCE STATEMENTS

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

---

**DATE SIGNED:** 10-09-03
Customer ID and Site Address:

ID: 11697
Institute For Biomedical Research
Hackensack, NJ 07601
County: Bergen

Telephone
(201)996-2879
### ANNUAL REPORT OF RESEARCH FACILITY

**TYPE OR PRINT**

**UNITED STATES DEPARTMENT OF AGRICULTURE**

**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**ANNUAL REPORT OF RESEARCH FACILITY**

**QUALTECH LABORATORIES, INC.**

104 Green Grove Road
Ocean, NJ 07712

Telephone: (908) 918-0207

**732**

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

**FACILITY LOCATIONS (Sites)** - See Attached Listing

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

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.</th>
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</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
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<td>9. Non-human Primates</td>
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</tr>
</tbody>
</table>

### ASSURANCE STATEMENTS

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

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

### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

**DATE SIGNED**

11-28-03
Kraft Foods North America, Inc  
Sherburne Pet Food Testing Center  
200 De Forest Avenue  
East Hanover, NJ  07936  
Telephone: (607) -674-9414

### REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes</th>
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<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS (C + D + E))</th>
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<tbody>
<tr>
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<tr>
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### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

Signature of C.E.O.  

[Signature]  

Date Signed  

10/30/03

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

(AUG 91)
### UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

### ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

**Gibraltar Laboratories, Inc.**
122 Fairfield Road
Fairfield, NJ 07004
Telephone: (973) -227-6882

---

### FACILITY LOCATIONS (Sites) - See Attached Listing

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

<table>
<thead>
<tr>
<th>Animals Covered By The Animal Welfare Regulations</th>
<th>Number of animals used for teaching, research, experiments, or tests conducted involving no pain, distress, or use of pain-relieving drugs</th>
<th>Number of animals upon which teaching, research, experiments, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
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<tr>
<td>5. Cats</td>
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<td>8. Rabbits</td>
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<tr>
<td>9. Non-human Primates</td>
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<tr>
<td>10. Sheep</td>
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<tr>
<td>11. Pigs</td>
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<tr>
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<tr>
<td>13. Other Animals</td>
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### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(Signature)

_Date Signed: 9/19/03_

APHIS FORM 7023
(Replaces VS FORM 18-23 (OCT 86), which is obsolete.)

(AUG 91)
### ANNUAL REPORT OF RESEARCH FACILITY

#### (TYPE OR PRINT)

<table>
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<th>A. Animals Covered by The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.</th>
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<tbody>
<tr>
<td>4. Dogs</td>
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<td>5. Cats</td>
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<tr>
<td>7. Hamsters</td>
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#### CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

<table>
<thead>
<tr>
<th>SIGNATURE OF C.I</th>
<th>DATE SIGNED</th>
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<td>10/29/03</td>
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APHIS FORM 7023

(AUG 91)
**ANNUAL REPORT OF RESEARCH FACILITY**

**TYPE OR PRINT**

**UNITED STATES DEPARTMENT OF AGRICULTURE**

**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**SCIENCE HALL ROOMS 206-208**

**FACILITY LOCATIONS (Sites)**

- **See Attached Listing**

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY**

(Attach additional sheets if necessary or use APHIS Form 7023A)

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
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</tr>
</thead>
<tbody>
<tr>
<td>4. Dogs</td>
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<td></td>
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<td>5. Cats</td>
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<td>6. Guinea Pigs</td>
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<td>7. Hamsters</td>
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<td>8. Rabbits</td>
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<td>9. Non-human Primates</td>
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<td>10. Sheep</td>
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<td>11. Pigs</td>
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<tr>
<td>12. Other Farm Animals</td>
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<tr>
<td>13. Other Animals</td>
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</tbody>
</table>

**ASSURANCE STATEMENTS**

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

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

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

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

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**

(Chief Executive Officer or Legally Responsible Institutional Official)

SIGN: __________________________

DATE SIGNED: ____________________

APHIS FORM 7023

(Replaces APHIS Form 18-23 (Jul 89), which is obsolete.)

(AUG 91)
ANNUAL REPORT OF RESEARCH FACILITY

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

FACILITY LOCATIONS (Sites) - See Attached Listing

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

<table>
<thead>
<tr>
<th>A. Animals Covered By The Animal Welfare Regulations</th>
<th>B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.</th>
<th>C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.</th>
<th>D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>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 appropriate anesthetic, analgesic, or tranquilizing drugs were used.</th>
<th>F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)</th>
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</thead>
<tbody>
<tr>
<td>Dogs</td>
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<tr>
<td>Cats</td>
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<td>Guinea Pigs</td>
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<td>Hamsters</td>
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<td>Pigs</td>
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<td>Other Farm Animals</td>
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<td>Other Animals</td>
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</table>

ASSURANCE STATEMENTS

1. Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual 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 to 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 assure 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)
Customer ID and Site Address:

ID: 22320
11 Deer Park Drive
Suite 117
Monmouth Junction, NJ 08852 1923
County: Middlesex

Telephone 732-438-9437 Ext 25
Registration Number: 22-R-0036

November 22, 2003

Elizabeth Goldentyer, DVM
UNITED STATES DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service
Regulatory Enforcement and Animal Care
Eastern Region Office
920 Main Campus Drive
Suite 200
Raleigh, NC 27605

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.