

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

12-10-2001 RCVD

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

Telephone: (908) -582-5696

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

FACILITY LOCATIONS (Sites) - See Attached Listing

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

| A. | B. | C. | D. | E. | F. |
|---|--|--|---|---|--|
| Animals Covered By The Animal Welfare Regulations | Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet | Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a | 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 | TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E) |
| 4. Dogs | | | | | 0 |
| 5. Cats | | | | | 0 |
| 6. Guinea Pigs | | | | | 0 |
| 7. Hamsters | | | | | 0 |
| 8. Rabbits | | | | | 0 |
| 9. Non-human Primate | | | No Covered Species | | 0 |
| 10. Sheep | | | | | 0 |
| 11. Pigs | | | | | 0 |
| 12. Other Farm Animals | | | | | 0 |
| 13. Other Animals | | | | | |

ASSURANCE STATEMENTS

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

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

SIC

DATE SIGNED

12/7/01

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

1. REGISTRATION NO. CUSTOMER NO.
22-R-0005 8203

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,
include Zip Code)
N J STATE DEPT OF HEALTH & Sr. Srv.
CN 360
TRENTON, NJ 08625
(609) 292-5847

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

FACILITY LOCATIONS(sites)

See Attached Listing

Laboratory Bldg - PH&FL

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

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

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

10/11/91

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)**
12-03-2001 RCVD

1. REGISTRATION NO. Customer No.
22-R-0012 172

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
ETHICON, INC.
P.O. Box 151
Somerville, NJ 08876
(908) 218-2172

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

FACILITY LOCATIONS (Sites)

ETHICON, INC.
P.O. BOX 151

SOMERVILLE, NJ 08876

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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). | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report). | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|---|---|--|
| 4. Dogs | | | 6 | | 6 |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | 5 | | | | 5 |
| 9. Non-human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | 549 | | 549 |
| 12. Other Farm Animals | | | | | |
| Goats | 9 | | 61 | | 61 |
| 13. Other Animals | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
4. The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0013 CUSTOMER NO. 163

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)
12-04-2001 RCVD

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

WORLDWIDE MOBILE VETERINARY UNIT
8 FOX HUNT DRIVE
ROCKAWAY, NJ 07866
(973) 538-6601

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|---|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | 44 | | 44 |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| . | | | | | |

ASSURANCE STATEMENTS

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

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

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

Si

DATE SIGNED

11/30/01

HEADQUARTERS

(AUG 91)

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0014 164

FORM APPROVED
OMB NO. 0579-0036

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

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,
include Zip Code)
NOVARTIS CORPORATION
PHARMACEUTICALS DIVISION
556 MORRIS AVENUE
SUMMIT, NJ 07901
(908) 277-6596

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

FACILITY LOCATIONS(sites)

See Attached Listing

10/1/00 - 9/30/01

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|---|--|--|--|--|---|
| 4. Dogs | - | 24 | 34 | | 58 |
| 5. Cats | - | - | - | | - |
| 6. Guinea Pigs | - | 162 | 288 | | 450 |
| 7. Hamsters | - | 108 | 137 | | 245 |
| 8. Rabbits | - | - | 486 | | 486 |
| 9. Non-Human Primates | 221 | 12 | 79 | | 91 |
| 10. Sheep | - | - | - | | - |
| 11. Pigs | - | - | - | | - |
| 12. Other Farm Animals | | | | | |
| Goats | - | - | 12 | | 12 |
| 13. Other Animals | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

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

DATE SIGNED

11/29/01

HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0016 174

FORM APPROVED
OMB NO. 0579-0036

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

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
JOHNSON & JOHNSON CONSUMER PRODUCTS, INC.
RESEARCH & DEVELOPMENT
199 GRANDVIEW ROAD
SKILLMAN, NJ 08558
(908) 874-1461

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

FACILITY LOCATIONS(sites)

See Attached Listing

J&J CONSUMER PRODUCTS W.D.

SKILLMAN, NJ

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|---|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | 256 | | 256 |
| 7. Hamsters | | 4 | | | |
| 8. Rabbits | | 89 | 10 | | 99 |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | 40 | 30 | | 70 |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| : | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

17/01

ARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. #175
22-R-0020
2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) University of Medicine & Dentistry
185 South Orange Avenue
MSB A-604
Newark, NJ 07103-2714
Status: Active

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

FACILITY LOCATIONS (Sites)

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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). | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report). | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|---|---|--|
| 4. Dogs | | | 73 | | 73 |
| 5. Cats | | | 49 | | 49 |
| 6. Guinea Pigs | | | 12 | | 12 |
| 7. Hamsters | | 1 | | | 1 |
| 8. Rabbits | | | 189 | | 189 |
| 9. Non-human Primates | | | 9 | | 9 |
| 10. Sheep | | | 0 | | 0 |
| 11. Pigs | | | 55 | | 55 |
| 12. Other Farm Animals | | | 0 | | 0 |
| 13. Other Animals | | | | | |
| Gerbils | | 6 | 40 | | 46 |
| S.A. Opossum | 25 | | 12 | | 37 |

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/29/01

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

| | | |
|---|---------------------|------------------------------------|
| 1. REGISTRATION NO. 22-R-0022 | CUSTOMER NO. 176 | FORM APPROVED OMB NO. 0579-0036 |
| 2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) PRINCETON UNIVERSITY OFFICE OF RESEARCH & PROJECTS P.O. BOX 36 PRINCETON, NJ 08544-0036 | | |

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

FACILITY LOCATIONS(sites)

| | |
|---|--|
| MOLECULAR/EVOLUTIONARY BIOLOGY PRINCETON, NJ 08544 | |
| | |

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|---|---|--|---|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | 23 | | 23 |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | 21 | | 21 |
| 9. Non-Human Primates | 14 | 5 | 6 | | 11 |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| Gerbils | | | 12 | | 12 |
| Peromyscus mice | | 498 | | | 498 |
| Squirrels | | 2 | | | 2 |

ASSURANCE STATEMENTS

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

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

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

| | | |
|---|--|-------------|
| SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) | DATE SIGNED |
| | | 11/30/2001 |

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0025 177

FORM APPROVED
OMB NO. 0579-0036

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

12-05-2001 RCVD

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
RUTGERS-STATE UNIVERSITY OF NJ
RESEARCH & SPONSORED PROGRAMS
P.O. BOX 1059
PISCATAWAY, NJ 08854
(908) 932-2880

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | | 29 | | | 29 |
| 5. Cats | | 3 | | | 3 |
| 6. Guinea Pigs | | 262 | | | 262 |
| 7. Hamsters | | 130 | | | 130 |
| 8. Rabbits | 8 | 2 | 15 | | 17 |
| 9. Non-Human Primates | | | 6 | | 6 |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| Deer | 6 | 4 | | | 4 |
| 13. Other Animals | | | | | |
| Hedgehog | | 1 | | | 1 |
| Ferret | | 46 | | | 46 |
| Spiny Mice | | 34 | | | 34 |

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11-30-01

b

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 22-R-0025
Customer Number: 177
Facility: RUTGERS-STATE UNIVERSITY OF NJ
RESEARCH & SPONSORED PROGRAMS
P.O. BOX 1059
PISCATAWAY, NJ 08854
(908) 932-2880

*PLEASE NOTE NEW ADDRESS:

3 Rutgers Plaza
New Brunswick, NJ 08901
(732) 932-0150

NOT A FOIA DELETION

BIOLOGY DEPT. CAMDEN CAMPUS
P.O. BOX 1059
BLDG 7002 SCIENCE
CAMDEN, NJ 08101

N.J. AGRICULTURAL EXPER. STATION
PSARF COMPLEX & BARTLETT HALL
NEW BRUNSWICK, NJ 08901

SMITH AND AIDEKMAN HALL
197 UNIVERSITY AVENUE
NEWARK, NJ 07102

PSYCH DEPT BLDG 3863 BUSH CAMP
3559D NELSON LABS & ANNEX
BEVIER ROAD
PISCATAWAY, NJ 08855

BIOLOGY DEPT. CAMDEN CAMPUS
P.O. BOX 1059
BLDG 7002 SCIENCE
CAMDEN, NJ 08101

DUPLICATE

*Please update your records to reflect the new Institutional Official as:

Rutgers, The State University of New Jersey
3 Rutgers Plaza
New Brunswick, NJ 08901
(732) 932-0150x
(732) 932-0145 Fax

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0028 168

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NJ 08543
(609) 252-4000

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

FACILITY LOCATIONS(sites)

See Attached Listing

Somerville, NJ

Attachment A #3

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | 128 | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

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UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0028 168

FORM APPROVED
OMB NO. 0579-0036

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

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,
include Zip Code)
BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NJ 08543
(609) 252-4000

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

FACILITY LOCATIONS(sites)

See Attached Listing

Hopewell (Pennington) NJ

Attachment A #4

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | | | 60 | | 60 |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | 111 | | | 111 |
| 7. Hamsters | | 173 | | | 173 |
| 8. Rabbits | | 76 | 150 | | 226 |
| 9. Non-Human Primates | | 29 | 76 | | 105 |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

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UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0028 168

FORM APPROVED
OMB NO. 0579-0036

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

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NJ 08543
(609) 252-4000

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

FACILITY LOCATIONS(sites)

See Attached Listing

Mount Vernon (Evansville) IN

Attachment D

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | 82 | 6 | 117 | 0 | 123 |
| 5. Cats | 0 | 0 | 0 | 0 | 0 |
| 6. Guinea Pigs | 0 | 0 | 0 | 0 | 0 |
| 7. Hamsters | 0 | 0 | 0 | 0 | 0 |
| 8. Rabbits | 34 | 0 | 98 | 0 | 98 |
| 9. Non-Human Primates | 0 | 10 | 1 | 0 | 11 |
| 10. Sheep | 0 | 0 | 0 | 0 | 0 |
| 11. Pigs | 0 | 0 | 0 | 0 | 0 |
| 12. Other Farm Animals | 0 | 0 | 0 | 0 | 0 |
| 13. Other Animals | 0 | 0 | 0 | 0 | 0 |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

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11/21/11
ADQUARTERS

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Appendix B

**Facility Location List
Revised 11/21/01
For 22-R-0028**

Page B1 of 3

ATTACHMENT B

**Location of BMS - Research Facilities
(Revised 11/21/01)**

Licensee/Registrant Name: Bristol-Myers Squibb Company

Licensee/Registrant Number: 22-R-0028

A. New Jersey (All within 35 mile radius)

#1 Name/Department: Veterinary Sciences
Address: Route 206 & Provinceline Road
Lawrenceville, NJ 08648

Building: G1 and G2
Floor/Room: Floors 2,3, and 4 for both buildings

Contact Person: [REDACTED] Telephone: [REDACTED]

#2 Name/Department: Veterinary Sciences
Address: One Squibb Drive
New Brunswick, NJ 08903

Building: 83, 125, 133, and 134
Floor/Room: NA

Contact Person: [REDACTED] Telephone: [REDACTED]

#3 Name/Department: Veterinary Sciences
Address: 76 Fourth Street
Somerville, NJ 08876

Building: NA
Floor/Room: NA

Contact Person: [REDACTED] Telephone: [REDACTED]

#4 Name/Department: Veterinary Sciences
Address: 311 Pennington-Rocky Hill Road
Pennington, NJ 08543

Building: 17
Floor/Room: NA

Contact Person: [REDACTED] Telephone: [REDACTED]

ATTACHMENT B (continued)

**Location of BMS - Research Facilities
(Revised 11/21/01)**

Licensee/Registrant Name: Bristol-Myers Squibb Company

Licensee/Registrant Number: 22-R-0028

B. Connecticut

Name/Department: Bristol-Myers Squibb Company

Address: 5 Research Parkway

POB 368

Wallingford, CT 06492-7660

Building: Vivarium

Floor/Room: N/A

Contact Person:

Telephone:

C. New York

Name/Department: Bristol-Myers Squibb Company

Address: POB 4755

6000 Thompson Road

East Syracuse, NY 13221-4755

Building: 32,32A,6A

Floor/Room: N/A

Contact Person:

Telephone:

D. Indiana

Name/Department: Bristol-Myers Squibb Company

Address: 2400 W. Lloyd Expressway

Building: 101

Floor/Room: N/A

Contact Person:

Telephone:

E. Delaware

Name/Department: Bristol-Myers Squibb Company

Address: Rt. 141 & Henry Clay Road

Building: E400

Floor/Room: N/A

Contact Person:

Telephone:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0031 CUSTOMER NO. 179

FORM APPROVED
OMB NO. 0579-0036

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

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA.
include Zip Code)
NEWARK BETH ISRAEL MEDICAL CENTER
201 LYONS AVENUE
NEWARK, NJ 07112

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

FACILITY LOCATIONS(sites)

NEWARK BETH ISRAEL MED CTR
NEWARK, NJ 07112

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|---|---|--|---|--|---|
| 4. Dogs | | | 62 | | 62 |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | 25 | | 25 |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/16/2001

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0034 CUSTOMER NO. 727

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,
include Zip Code)
NEXTRAN COMPANY
303-B COLLEGE ROAD EAST
PRINCETON, NJ 08540

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

FACILITY LOCATIONS(sites)

NEXTRAN COMPANY
ALBANY, OH 45710

ROCHESTER SWINE FACILITY
ROCHESTER, MN 55901

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|---|---|--|---|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | 376 | 480 | 930 | | 1410 |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/06/2001

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 22-R-0034
Customer Number: 727
Facility: NEXTRAN COMPANY
303-B COLLEGE ROAD EAST
PRINCETON, NJ 08540
(609) 243-0009

NEXTRAN COMPANY
901 CARPENTER RD.
ALBANY, OH 45710

ROCHESTER SWINE FACILITY
3400 22ND ST NW
ROCHESTER, MN 55901

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

DEC 17 2001

| | | |
|---|---------------------|------------------------------------|
| 1. REGISTRATION NO. 22-P-0037 | CUSTOMER NO. 752 | FORM APPROVED OMB NO. 0579-0036 |
| 2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) RIDER UNIVERSITY 2083 LAWRENCEVILLE ROAD LAWRENCEVILLE, NJ 08648 (609) 896-5010 | | |

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| Spiny Mice | 300 | 200 | 0 | 0 | 200 |
| 13. Other Animals | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL

DATE SIGNED

12-12-01

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

See reverse side for additional information.

CR
Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0038 677

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

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

BRACCO RESEARCH USA INC.
305 COLLEGE ROAD EAST
PRINCETON, NJ 08540
(609) 514-2437

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| (4-13) | 0 | 0 | 0 | 0 | |
| 13. Other Animals | | | | | |
| | | | | (only rats & 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, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

DATE SIGNED

10/20/01

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 22-R-0038
Customer Number: 677
Facility: BRACCO RESEARCH USA INC.
305 COLLEGE ROAD EAST
PRINCETON, NJ 08540
(609) 514-2437

BRACCO RESEARCH USA INC.
305 COLLEGE ROAD EAST
PRINCETON, NJ 08540

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0043 CUSTOMER NO. 991

FORM APPROVED
OMB NO. 0579-0036

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

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

CELSIS, INC.
NEW JERSEY DIVISION
165 FIELDCREST AVENUE
EDISON, NJ 08837
(908) 245-1933

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

FACILITY LOCATIONS(sites)

See Attached Listing

Celsis Laboratory Dept - NJ
Edison, NJ 08837

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|--|---|---|--|--|---|
| 4. Dogs | 0 | 0 | 0 | 0 | 0 |
| 5. Cats | 0 | 0 | 0 | 0 | 0 |
| 6. Guinea Pigs | 0 | 0 | 0 | 0 | 0 |
| 7. Hamsters | 0 | 0 | 0 | 0 | 0 |
| 8. Rabbits | 0 | 0 | 0 | 0 | 0 |
| 9. Non-Human Primates | 0 | 0 | 0 | 0 | 0 |
| 10. Sheep | 0 | 0 | 0 | 0 | 0 |
| 11. Pigs | 0 | 0 | 0 | 0 | 0 |
| 12. Other Farm Animals | 0 | 0 | 0 | 0 | 0 |
| 13. Other Animals | 0 | 0 | 0 | 0 | 0 |
| | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

SIGN

AL (Type or Print)

DATE SIGNED

11/12/01

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0064 CUSTOMER NO. 182

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA.
include Zip Code)
ORTHO-CLINICAL DIAGNOSTICS, INC.
REGULATORY & CLINICAL AFFAIRS
1001 U.S. HIGHWAY 202
RARITAN, NJ 08869
(908) 218-8177

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

FACILITY LOCATIONS(sites)

| See Attached Listing | SITE 001 | SITE 002 |
|--|--|----------|
| Ortho-Clinical Diagnostics Inc. 1001 US Hwy 202 | Sterlingbrook Equine Trauma Center PO. Box 609 RT 513 | |
| Raritan, NJ 08869 | Pittstown, NJ | |

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|--|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | 125 | 581 | | 706 |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| Goats | 1 | 19 | | | 19 |
| 13. Other Animals | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/14/91

QUARTERS

(AUG 91)

APHIS Form 7023 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 & CLINICAL AFFAIRS
1001 U.S. HIGHWAY 202
RARITAN, NJ 08869
(908) 218-8177

ANIMAL RAW MATERIAL
BUILDING K
ROUTE 202
RARITAN, NJ 08869

STERLINGBROOK EQUINE TRAUMA CENTER
CITY ROUTE 513 BOX 344
PITTSTOWN, NJ 08867

ORTHO-CLINICAL DIAGNOSTICS, INC
1001 U.S. HIGHWAY 202
RARITAN, NJ 08869

STERLINGBROOK EQUINE TRAUMA CENTER
CITY ROUTE 513 BOX 344
PITTSTOWN, NJ 08867

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0065 183

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA.
Include Zip Code)
WILLIAM PATERSON UNIVERSITY OF NEW JERSEY
300 POMPTON ROAD
WAYNE, NJ 07470
(973) 720-2480

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

FACILITY LOCATIONS(sites)

See Attached Listing

SCIENCE HALL ROOMS 206-208

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

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

ASSURANCE STATEMENTS

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

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

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

S

DATE SIGNED

11/9/01

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0066 CUSTOMER NO. 184

FORM APPROVED
OMB NO. 0579-0306

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA.
(include Zip Code)
UNIVERSITY OF MEDICINE & DENTISTRY OF NJ
675 HOES LANE
PISCATAWAY, NJ 08854
(908) 235-4687

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|---|--|---|
| 4. Dogs | 2 | 0 | 96 | 0 | 96 |
| 5. Cats | 0 | 0 | 0 | 0 | 0 |
| 6. Guinea Pigs | 0 | 0 | 2 | 0 | 2 |
| 7. Hamsters | 0 | 4 | 0 | 0 | 4 |
| 8. Rabbits | 0 | 0 | 316 | 0 | 316 |
| 9. Non-Human Primates | 0 | 0 | 0 | 0 | 0 |
| 10. Sheep | 4 | 0 | 17 | 0 | 17 |
| 11. Pigs | 0 | 0 | 32 | 0 | 32 |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

10/15/01

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 22-R-0066
Customer Number: 184
Facility: UNIVERSITY OF MEDICINE & DENTISTRY OF NJ
675 HOES LANE
PISCATAWAY, NJ 08854
(908) 235-4687

VIVARIUM
EDUCATION AND RESEARCH BUILDING
401 HADDON AVE
CAMDEN, NJ 08103

UMDNJ-ROBERT WOOD JOHNSON MEDICAL EDUCATION BLDG.
MEDICAL EDUCATION BUILDING
ONE ROBERT WOOD JOHNSON PLACE
NEW BRUNSWICK, NJ 08903

RESEARCH TOWER & RUTGERS, NELSON BIO
BASIC SCIENCE BUILDING
675 HOES LANE
PISCATAWAY, NJ 08854

WEST JERSEY BIOSERVICES INC.
WEST JERSEY BIOSERVICES
SOUTH MARION AVE.
WENONAH, NJ 08090

[REDACTED]
BARTON'S WEST END FACILITIES
161 JANE'S CHAPEL ROAD
OXFORD, NJ 07863

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

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0076 189

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)
11-26-2001 RCVD

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,
include Zip Code)
CAMDEN COUNTY COLLEGE
P.O. BOX 200
COLLEGE DRIVE
BLACKWOOD, NJ 08012
(609) 227-7200

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

FACILITY LOCATIONS(sites)

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

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/15/01

HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0088 CUSTOMER NO. 192

FORM APPROVED
OMB NO. 0579-0036

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

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

F M C CORPORATION
BOX 8
PRINCETON, NJ 08543

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

FACILITY LOCATIONS(sites)

TOXICOLOGY LABORATORY
PRINCETON, NJ 08543

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | 79 | | | 79 |
| 7. Hamsters | | | | | |
| 8. Rabbits | | 156 | 3 | | 159 |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| | | | | | |
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ASSURANCE STATEMENTS

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

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

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

| SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) | DATE SIGNED |
|---|--|-------------|
| | | 11/16/2001 |

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

| | | |
|---|---------------------|------------------------------------|
| 1. REGISTRATION NO. 22-R-0099 | CUSTOMER NO. 194 | FORM APPROVED OMB NO. 0579-0036 |
| 2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) | | |
| UNIVERSITY OF MEDICINE & DENTISTRY OF NJ 2 MEDICAL CENTER DRIVE STRATFORD, NJ 08084 | | |

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

FACILITY LOCATIONS(sites)

UNIVERSITY OF MEDICINE AND DENISTRY OF NJ
STRATFORD, NJ 08084

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

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

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/28/2001

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

| | | |
|--|---------------------|------------------------------------|
| 1. REGISTRATION NO. 22-R-0104 | CUSTOMER NO. 198 | FORM APPROVED OMB NO. 0579-0036 |
| 2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) | | |
| CENTER FOR MOLECULAR MED & IMMUNOLOGY 520 BELLVILLE AVE BELLEVILLE, NJ 07109 (201) 844-7000 | | |

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|--|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | 93 | | 93 |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| Mice | | 300 | 7772 | | 8072 |
| Rats | | | 9 | | 9 |
| . | | | | | |

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF

DATE SIGNED

10/24/01

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0110 CUSTOMER NO. 8209

FORM APPROVED
OMB NO. 0579-C036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

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

MORRISTOWN MEMORIAL HOSPITAL
100 MADISON AVENUE
MORRISTOWN, NJ 07962
(973) 971-6256

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

FACILITY LOCATIONS(sites)

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

ASSURANCE STATEMENTS

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

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

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

DATE SIGNED

12/17/01

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 22-R-0110
Customer Number: 8209
Facility: MORRISTOWN MEMORIAL HOSPITAL
100 MADISON AVENUE
MORRISTOWN, NJ 07962
(973) 971-6256

REEVES SURGICAL LABORATORY
MADISON AVENUE CAMPUS
MORRISTOWN, NJ 07962

Spw

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0115 CUSTOMER NO. 714

FORM APPROVED
OMB NO. 0579-0036

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

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

COSOMOPOLITAN SAFETY EVALUATION, INC.
P.O. BOX 71
LAFAYETTE, NJ 07848
(201) 383-6253

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|---|--|--|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

COMPANY

ROGED

NO OFFICERS.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0116 695

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT) 26-2001 RCVD

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

XENOBIOTIC LABORATORIES, INC.
107 MORGAN LANE
PLAINSBORO, NJ 08536
(609) 799-2295

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

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | 0 | 11 | 0 | 0 | 11 |
| 5. Cats | 1 | 0 | 0 | 0 | 1 |
| 6. Guinea Pigs | | | 1 | | |
| 7. Hamsters | | | 1 | | |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | ↓ | ↓ | ↓ | ↓ | ↓ |
| .. | | | | | |

ASSURANCE STATEMENTS

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

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

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

| | |
|----------------------|-------------|
| Sign (Type or Print) | DATE SIGNED |
| | 11-19-01 |

PART 1 - HEADQUARTERS

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

See reverse side for
additional information.

Interagency Report Control No
0180-DOA-AN

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

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

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

BARTON'S WEST END FARMS, INC.
161 JANES CHAPEL ROAD
OXFORD, NJ 07863
(908) 637-4427

See Attached Listing
Barton's West End Farms, Inc.
161 Janes Chapel Road Oxford, NJ 07863
Alder Ridge Farms, Inc.
P O Box 290 Lakewood, PA 18439-0290

FACILITY LOCATIONS (sites)

ASSURANCE STATEMENTS

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

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

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SIAL (Type or Print)

DATE SIGNED

10-9-01

PART 1 - HEADQUARTERS

Opr

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0118 1672

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

11-05-2001 RCV

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

PEDIATRIC CARDIOLOGY
137 PAVILION AVENUE
LONG BRANCH, NJ 07740
(908) 870-1611

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|---|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | | | |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | does not apply because I am not doing any animal experiments so far | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

SIGN

DATE SIGNED

18/19/07

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

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0120 CUSTOMER NO. 1701

FORM APPROVED
OMB NO. 0579-0036

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

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

QUALTECH LABORATORIES, INC.
104 GREEN GROVE ROAD
OCEAN, NJ 07712
(908) 918-0207

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

FACILITY LOCATIONS(sites)

See Attached Listing

As above

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|---|---|--|---|--|---|
| 4. Dogs | 0 | 0 | 0 | 0 | 0 |
| 5. Cats | 0 | 0 | 0 | 0 | 0 |
| 6. Guinea Pigs | 0 | 0 | 0 | 0 | 0 |
| 7. Hamsters | 0 | 0 | 0 | 0 | 0 |
| 8. Rabbits | 0 | 0 | 0 | 0 | 0 |
| 9. Non-Human Primates | 0 | 0 | 0 | 0 | 0 |
| 10. Sheep | 0 | 0 | 0 | 0 | 0 |
| 11. Pigs | 0 | 0 | 0 | 0 | 0 |
| 12. Other Farm Animals | 0 | | | | |
| 13. Other Animals | 0 | 0 | 0 | 0 | 0 |
| | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

DATE SIGNED

11-26-01

1 - HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0122 1804

FCRM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT) 30-2001 RCV

(TYPE OR PRINT) 30-2001 RCVD

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

EpiGenesis Pharmaceuticals, Inc.
7 Clarke Drive
Trenton, NJ 08512

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

FACILITY LOCATIONS(sites)

See Attached Listing

One Location

2005 EastPark Blvd, Cranbury, NJ 08512

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

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)

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

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

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11 / 29 / 0

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PART 1 - HEADQUARTERS

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

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0123 1824

FORM APPROVED
OMB NO. 0579-0036

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

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

COUNTY COLLEGE OF MORRIS
214 CENTER GROVE ROAD
RANDOLPH, NJ 07869
(999) 999-9999

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

FACILITY LOCATIONS(sites)

See Attached Listing

County College of Morris

Sheffield Hall A 230

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|---|---|--|---|--|---|
| 4. Dogs | 0 | 0 | 0 | 0 | 0 |
| 5. Cats | 0 | 0 | 0 | 0 | 0 |
| 6. Guinea Pigs | 0 | 0 | 0 | 0 | 0 |
| 7. Hamsters | 0 | 0 | 0 | 0 | 0 |
| 8. Rabbits | 0 | 4 | 0 | 0 | 4 |
| 9. Non-Human Primates | 0 | 0 | 0 | 0 | 0 |
| 10. Sheep | 0 | 0 | 0 | 0 | 0 |
| 11. Pigs | 0 | 0 | 0 | 0 | 0 |
| 12. Other Farm Animals | 0 | 0 | 0 | 0 | 0 |
| 13. Other Animals | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

DATE SIGNED

9/19/01

T 1 - HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0125 CUSTOMER NO. 11697

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

6/1/90 2081

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

HACKENSACK UNIVERSITY MEDICAL CENTER
INSTITUTE FOR BIOMEDICAL RESEARCH
DAVID JOSEPH JURIST RESEARCH BLDG
30 PROSPECT AVE
HACKENSACK, NJ 07601
(201) 996-2879

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|--|
| 4. Dogs | 4 | 0 | 52 | 0 | 52 |
| 5. Cats | 0 | 0 | 0 | 0 | 0 |
| 6. Guinea Pigs | 0 | 0 | 0 | 0 | 0 |
| 7. Hamsters | 0 | 0 | 0 | 0 | 0 |
| 8. Rabbits | 1 | 1 | 0 | 0 | 1 |
| 9. Non-Human Primates | 0 | 0 | 0 | 0 | 0 |
| 10. Sheep | 0 | 0 | 0 | 0 | 0 |
| 11. Pigs | 7 | 0 | 121 | 0 | 121 |
| 12. Other Farm Animals | 0 | 0 | 0 | 0 | 0 |
| 13. Other Animals | | | | | |
| Woodchucks | 5 | 0 | 25 | 0 | 25 |

ASSURANCE STATEMENTS

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

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APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 22-R-0125
Customer Number: 11697
Facility: HACKENSACK UNIVERSITY MEDICAL CENTER
INSTITUTE FOR BIOMEDICAL RESEARCH
DAVID JOSEPH JURIST RESEARCH BLDG
30 PROSPECT AVE
HACKENSACK, NJ 07601
(201) 996-2879

HACKSENACK UNIVERSITY MEDICAL CENTER
INSTITUTE FOR BIOMEDICAL RESEARCH
HACKENSACK, NJ 07601

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

See reverse side for
additional information.

Interagency Report Control No
0180-DOA-AN

| | | | |
|--|----------------------------------|-----------------------|------------------------------------|
| UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE | 1. REGISTRATION NO. 22-R-0129 | CUSTOMER NO. 13371 | FORM APPROVED OMB NO. 0579-0036 |
| ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT) | | | |
| 2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA. include Zip Code) MATRIX CHARITABLE INSTITUTE 65 RAILROAD AVE RIDGEFIELD, NJ 07657 (201) 945-5885 | | | |

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

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

FACILITY LOCATIONS(sites)

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

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)

SIG

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(AUG 91)

DATE SIGNED

DATE SIGNED
10/3/01

1 - HEADQUARTERS

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

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0130 CUSTOMER NO. 1701

FORM APPROVED
OMB NO. 0579-0036

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

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

QUALTECH LABORATORIES, INC.
104 GREEN GROVE ROAD
OCEAN, NJ 07712
(908) 918-0207

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

FACILITY LOCATIONS(sites)

See Attached Listing

As above

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|--|--|--|---|
| 4. Dogs | 0 | 0 | (b)(6), (b)(7)c 50 | 0 | 0 |
| 5. Cats | 0 | 0 | 5 | 0 | 5 |
| 6. Guinea Pigs | 0 | 0 | 0 | 0 | 0 |
| 7. Hamsters | 0 | 0 | 0 | 0 | 0 |
| 8. Rabbits | 0 | 0 | 0 | 0 | 0 |
| 9. Non-Human Primates | 0 | 0 | 0 | 0 | 0 |
| 10. Sheep | 0 | 0 | 0 | 0 | 0 |
| 11. Pigs | 0 | 0 | 0 | 0 | 0 |
| 12. Other Farm Animals | 0 | 0 | 0 | 0 | 0 |
| 13. Other Animals | 0 | 0 | 0 | 0 | 0 |
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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)**

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

DATE SIGNED

11-26-01

HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

| | | |
|---|---------------------|------------------------------------|
| 1. REGISTRATION NO. 22-R-0009 | CUSTOMER NO. 519 | FORM APPROVED OMB NO. 0579-0036 |
| 2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) NOVARTIS PHARMACEUTICALS CORPORATION NOVARTIS PHARMACEUTICALS CORPORATION BLDG 404, RM 466 EAST HANOVER, NJ 07936 (201) 386-7500 | | |

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

FACILITY LOCATIONS(sites)

| | |
|----------------------|--|
| 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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | 20 | 439 | 11 | 29 | 479 |
| 5. Cats | N/A | - | - | - | - |
| 6. Guinea Pigs | N/A | - | - | - | - |
| 7. Hamsters | N/A | - | - | - | - |
| 8. Rabbits | 9 | 263 | 0 | 6 | 269 |
| 9. Non-Human Primates | 368 | 293 | 11 | 29 | 333 |
| 10. Sheep | N/A | - | - | - | - |
| 11. Pigs | N/A | - | - | - | - |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |

ASSURANCE STATEMENTS

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

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

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

| | | |
|---|--|-------------|
| SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) | DATE SIGNED |
| | | 11/29/01 |

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PART 1 - HEADQUARTERS

(AUG 91)

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USDA ANNUAL REPORT OF RESEARCH FACILITY FOR 2000-2001
NOVARTIS PHARMACEUTICALS CORPORATION
USDA Registration No. 22-R-0009

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

| Protocol Title | Species | Number | Days Without Exercise | | Reason |
|--|---------|--------|-----------------------|---|--|
| | | | 1 | 2 | |
| 1. Relative Absorbance of Formulations of Compound X | Dogs | 3 | 14 | | Quantitative collection of excreta, containment of radioactivity |
| 2. Relative Absorbance of Formulations of Compound X | Dogs | 7 | 19 | | Quantitative collection of excreta, containment of radioactivity |
| 3. Relative Absorbance of Formulations of Compound X | Dogs | 8 | 9 | | Quantitative collection of excreta, containment of radioactivity |
| 4. Relative Absorbance of Formulations of Compound X | Dogs | 6 | 8 | | Quantitative collection of excreta, containment of radioactivity |
| 5. Relative Absorbance of Formulations of Compound X | Dogs | 2 | 4 | | Quantitative collection of excreta, containment of radioactivity |
| 6. Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys intended for use on Safety Pharmacology Studies | Dogs | 9 | 10 | | Surgical recovery of dogs implanted with telemetry devices |
| 7. Telemetry Device Implantation and Holding Protocol for Dogs and Monkeys intended for use on Safety Pharmacology Studies | Dogs | 1 | 8 | | Surgical recovery of dogs implanted with telemetry devices |
| 8. Training, Development and Refinement Procedures | Dogs | 2 | 10 | | Surgical recovery of dogs implanted with telemetry devices |

OPTIONAL COLUMN E EXPLANATION FORM

4-WEEK INTRAVENOUS TOXICOLOGY STUDY

1. Registration Number: 22-R-0009
2. Number of animals used in this study - 36. Number of animals classified as category "E" - 1.
3. Species (common name) _____ Common Marmoset _____ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These marmosets were dosed with a pharmaceutical compound.

On day 51 of the study, this marmoset experienced compound related effects and was euthanized.

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 indicative of pain and distress, the animal was euthanized.

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

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

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

OPTIONAL COLUMN E EXPLANATION FORM

2-WEEK RISING DOSE INTRAVENOUS MONKEY STUDY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 24. Number of animals classified as category "E" - 6.
3. Species (common name) _____ Crab-eating Macaque _____ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These primates were dosed with a pharmaceutical compound.

Six primates were euthanized on day 12 of this study after exhibiting 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)

As soon as there were signs indicating that these animals were experiencing pain or 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

SINGLE DOSE IV INFUSION IN A DOG WITH A 3 OR 12 WEEK RECOVERY

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 displayed compound related effects. One dog was euthanized on the same day as the clinical signs were noted. Veterinary treatment was administered to the remaining 3 dogs without success and the dogs were subsequently euthanized.

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 these animals were experiencing 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

**13-WEEK INTRAVENOUS INFUSION (ONCE TRI-WEEKLY DOSING)
TOXICOLOGY STUDY IN DOGS**

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 18. 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 demonstrated a non-weight bearing limb during this study due to compound-related effects. The dog was treated and the condition resolved. The dog was euthanized as scheduled.

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)
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 TELEMETRY 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" - 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 experienced compound related effects and were euthanized on days 8 & 9 of the study. The study was discontinued.

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 these animals were experiencing 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

2-WEEK ORAL (Gavage) TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 16. Number of animals classified as category "E" - 8.
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.

These animals displayed compound related effects and were euthanized.

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 these animals were experiencing pain or 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

TELEMETRY STUDY IN DOGS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 12. 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 implanted with telemetry devices.

One dog died 48 hours post-surgically from complications potentially due to clotting factor VII deficiency. In the future, clotting profiles will be performed prior to surgery.

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)
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

13-WEEK ORAL DOSING TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 58. 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 displayed compound related effects and was euthanized on the same day.

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 this 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

13-WEEK ORAL DOSING TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 22. 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.

These three dogs displayed compound related effects and were euthanized on the same day.

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 these animals were experiencing pain or 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

26-WEEK ORAL DOSING TOXICITY STUDY IN DOGS

1. Registration Number: 22-R-0009
2. Number of animals used in this study - 40. Number of animals classified as category "E" - 8.
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 were found dead with no prior clinical signs and five dogs displayed compound related effects. The eight dogs were in the high-dose group.

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 these animals were experiencing pain or distress, the dose of the compound was lowered.

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 DOSING TOXICITY STUDY IN MONKEYS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 40. Number of animals classified as category "E" - 15.
3. Species (common name) Crab-eating Macaque of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Fifteen animals displayed transient compound related effects and recovered in 2 - 6 hours.

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)
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

RISING DOSE 2-WEEK ORAL TOXICITY STUDY IN MONKEYS

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) Crab-eating Macaque of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

One animal was found dead with no prior clinical signs. Five animals displayed compound related effects and were euthanized on the same day as the signs were noted.

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 these animals were experiencing pain or 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

A MODIFIED INTRAVENOUS RISING DOSE TOXICITY STUDY IN MONKEYS

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) __Crab-eating Macaque__ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

One animal was found dead with no prior clinical signs.

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

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

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

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) 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 was found dead with no prior clinical signs and two rabbits were euthanized after displaying 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)

As soon as there were signs indicating that these animals were experiencing pain or 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).
- 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
AN EMBRYO-FETAL DEVELOPMENT DOSE RANGE FINDING STUDY IN
RABBITS

1. Registration Number: 22-R-0009

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

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 was found dead with no prior clinical signs. One rabbit exhibited compound-related effects and was euthanized.

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 this animal was experiencing pain or distress, it was euthanized.

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

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

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

OPTIONAL COLUMN E EXPLANATION FORM

AN 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" - 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 was found dead with no prior clinical signs.

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

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

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

| | | |
|--|---------------------|------------------------------------|
| 1. REGISTRATION NO. 22-R-0032 | CUSTOMER NO. 180 | FORM APPROVED OMB NO. 0579-0036 |
| 2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA. include Zip Code) HOFFMANN-LAROCHE, INC. RESEARCH & DEVELOPMENT DIV. 340 KINGSLAND STREET NUTLEY, NJ 07110 (201) 235-5000 | | |

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

FACILITY LOCATIONS(sites)

See Attached Listing

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|---|---|--|---|--|---|
| 4. Dogs | 20 | 266 | 0 | 4 | 270 |
| 5. Cats | 0 | 0 | 0 | 0 | 0 |
| 6. Guinea Pigs | 0 | 324 | 0 | 0 | 324 |
| 7. Hamsters | 0 | 0 | 0 | 0 | 0 |
| 8. Rabbits | 0 | 54 | 0 | 0 | 54 |
| 9. Non-Human Primates | 17 | 14 | 27 | 0 | 41 |
| 10. Sheep | 0 | 0 | 0 | 0 | 0 |
| 11. Pigs | 0 | 0 | 0 | 0 | 0 |
| 12. Other Farm Animals | 0 | 0 | 0 | 0 | 0 |
| 13. Other Animals | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

Apprv'd As To Form
LAW DEPT.

By

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

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

| | | |
|---|--|-------------|
| SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) | DATE SIGNED |
| | | 11-26-01 |

QAW

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 22-R-0032.
Customer Number: 180
Facility: HOFFMANN-LAROCHE, INC.
RESEARCH & DEVELOPMENT DIV.
340 KINGSLAND STREET
NUTLEY, NJ 07110
(201) 235-5000

HOFFMANN LAROCHE
BUILDINGS 34, 76, 100
340 KINGSLAND ST.
NUTLEY, NJ 07110

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 4 of animals used in this study.

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

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

See attached

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 21 CFR 58.3(d)
21 CFR 58.90

HOFFMANN-LA ROCHE
22-R-0032

USDA CATEGORY E description:

DOGS:

A total of 4 dogs from a group used in studies to evaluate drug candidates for clinical trials were identified as Category E. The dogs were used to evaluate an anti-asthmatic 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 on a daily basis and provide supportive care when needed.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0036 CUSTOMER NO. 181

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

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

SCHERING CORPORATION
2015 GALLOPING HILL ROAD
KENILWORTH, NJ 07033
(908) 298-4000

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

FACILITY LOCATIONS(sites)

Schering-Plough Research Institute
2015 Galloping Hill Rd., Kenilworth, NJ 07033
Schering-Plough Research Institute, Safety Evaluation Center
P.O. Box 32, Lafayette, NJ 07848

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

| A. | B. Number of animals covered by the Animal Welfare Regulations | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO OF ANIMALS (Cols. C + D + E) |
|------------------------|--|---|---|--|--|
| 4. Dogs | 0 | 317 | 370 | 10 | 697 |
| 5. Cats | 0 | 0 | 25 | 0 | 25 |
| 6. Guinea Pigs | 0 | 6417 | 3069 | 0 | 9486 |
| 7. Hamsters | 2 | 28 | 66 | 0 | 94 |
| 8. Rabbits | 0 | 488 | 206 | 45 | 739 |
| 9. Non-Human Primates | 127 | 267 | 340 | 7 | 614 |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| Gerbils | 0 | 1300 | 4520 | 0 | 5820 |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

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

| | | | |
|------|--------|--|-----------------------|
| SIGN | FICIAL | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) | DATE SIGNED /29/01 |
|------|--------|--|-----------------------|

RAB

November 29, 2001

Elizabeth Goldentyer, DVM
UNITED STATES DEPARTMENT OF AGRICULTURE
Animal and Plan Health Inspection Service
Regulatory Enforcement and Animal Care
Eastern Region Office
920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Dear Dr. Goldentyer:

Listed below are comments to accompany the annual report of research facilities for site number 1.

The environmental enrichment program has exceptions for social housing for nonhuman primates. Seventeen squirrel monkeys and twenty-five rhesus monkeys are housed separately due to special study requirements for controlling and monitoring food consumption as part of the research projects. Four cynomolgus monkeys were housed separately while participating in drug metabolism 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.

Listed below are comments to accompany the annual report of research facilities for site number 2.

Listed below are instances wherein animals were exempted from the pair-housing requirement of our program for the psychological well-being of non-human primates. The duration of such exemptions varied according to the reason. The numbers of animals and reasons for such exemptions are herein listed:

1. Nearly all cynomolgus non-human primates were exempted from social housing for periods of time when required for collection of individual clinical signs, required randomization of the animals in studies, or during the quarantine period. The exemption from social housing was variable depending on the duration of the individual study. All study protocols were reviewed and approved by the IACUC.
2. Fifteen cynomolgus non-human primates were exempted from social housing due to a transient medical condition as specified by the Staff Veterinarian, the duration of the exemption varied depending upon the medical condition.
3. Nine cynomolgus non-human primates were exempted from social housing due to their being the documented aggressor in a pair-housing situation on at least two occasions.

There were 5 dogs exempted from the canine exercise program during the thirty-day dosing period of studies due to aggression. The exemption were reviewed and approved by the Attending Veterinarian.

The dogs, rabbits and nonhuman primates listed in column "E" were used in standard toxicological investigations for new drug development. Because one purpose of toxicological studies was to define the pharmacokinetic and metabolic profiles of new chemical entities, potential drug interactions were not known during the course of the studies. Administration of anesthetics, tranquilizers, and/or analgesics could result in additive toxicities which would be detrimental to the animal's well-being. In addition, close monitoring was critical to determine whether or not the compounds had any detrimental effects. These agents were, therefore, withheld in accordance with protocols which were carefully reviewed and approved by the IACUC. As a standard policy, the attending veterinarian is notified of any abnormal medical condition that may occur in any of the research animals. All animals were carefully monitored and if found to be in pain and/or distress during the course of the study were provided humane euthanasia.

Listed below are number of animals, and species that retrospectively and prospectively may have experienced more than momentary pain or distress during the study. All the studies are performed under GLP standards for possible FDA submission. The studies were conducted in accordance with FDA requirements [21CFR 312.23(a)(8), 21 CFR 58, 62 FR 62922, and 59 FR 48746] and the International Conference Harmonization Guidelines (M3).

One cynomolgus monkey and nine rabbits were on studies that the Institutional Animal Care and Use Committee (IACUC) had reviewed and determined were not reasonably expected to cause more than slight or momentary pain and/or distress. The one cynomolgus monkey developed unexpected medical complications and was provided palliative treatment to address the complications. When the cynomolgus monkey's complications became severe and took the subject outside of the approved protocol, the cynomolgus monkey was humanely euthanized. The nine rabbits developed unexpected medical complications which took the subjects outside of the approved protocol. These subjects are noted as having been terminated on the study.

Six cynomolgus monkeys and ten dogs were reported to have at least one emesis event during the study. In some test articles, emesis is a side effect so it is important to evaluate the drug and dose level for this problem. Although this may have caused some distress, all the animals on study remained healthy.

A study of 36 rabbits was used to determine if intramuscular injects of a test agent caused any local irritation. The IACUC had reviewed and determined that the study may cause more than momentary pain and/or distress. The FDA requires the study, because the test agent would be clinically dosed intramuscularly.

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

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUST. NO.
22-R-0041 173

FORM APPROVED
QMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (NAME AND ADDRESS, AS REGISTERED WITH USDA,
INCLUDE ZIP CODE)

BECTON DICKINSON AND CO.
ONE BECTON DRIVE
FRANKLIN LAKES, NJ 07417
(201) 847-6800

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

FACILITY LOCATIONS(S)

See Attached Listing

Becton Dickinson Technologies
21 Davis Drive

Research Triangle Park, NC
27709

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 70234.)

| A. | B. Number of animals covered by the Animal Welfare Regulations | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, disease, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Colz. C + D - E) |
|------------------------|--|--|---|--|--|
| 4. Dogs | | | | | 0 |
| 5. Cats | | | | | 0 |
| 6. Guinea Pigs | | 1610 | | 40 | 1650 |
| 7. Hamsters | | | | | 0 |
| 8. Rabbits | | 319 | 18 | | 337 |
| 9. Non-Human Primates | | | | | 0 |
| 10. Sheep | | | | | 0 |
| 11. Pigs | | | 273 | | 273 |
| 12. Other Farm Animals | | | | | 0 |
| 13. Other Animals | | | | | 0 |
| | | | | | |
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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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report, in addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

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

DATE SIGNED

Sept. 27,
2001

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.

22-R-0041

1. Registration Number: _____

2. Number 40 of animals used in this study.3. Species (common name) Guinea Pig of animals used in the study.

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

0.1 ml intradermal injection of Freund's Complete Adjuvant causes dermal irritation and ulceration at the injection site. One week following ID injection sites are irritated with 10% sodium Lauryl sulfate in petrolatum. The next day they are wrapped for 48 hours and upon binder removal the guinea pig scabs for orginal ID injection site are subsequently pulled off and causes bleeding on some.

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)

Pain medication could compromise the sensitization process.

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 21 CFR 58
ISO 10993:10

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

See reverse side for additional information.

RAB
Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0069 185

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

11-30-2001 RCVD

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

CONSUMER PRODUCT TESTING CO., INC.
70 NEW DUTCH LANE
FAIRFIELD, NJ 07004
(973) 227-808-7111

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|---|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | 24 | 2554 | 14 | 223 | 2791 |
| 7. Hamsters | 13 | 30 | 0 | 12 | 42 |
| 8. Rabbits | 54 | 907 | 0 | 156 | 1063 |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| . | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

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

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

DATE SIGNED

11/29/01

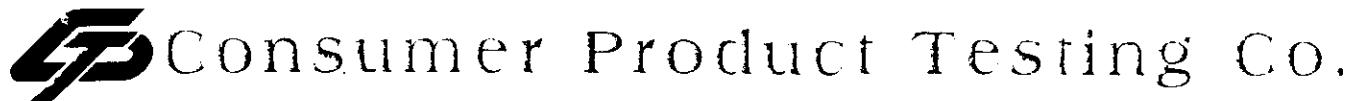
QCM

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 22-R-0069
Customer Number: 185
Facility: CONSUMER PRODUCT TESTING CO., INC.
70 NEW DUTCH LANE
FAIRFIELD, NJ 07004
(973) (201) 808-7111

CONSUMER PRODUCT TESTING
70 NEW DUTCH LANE
FAIRFIELD, NJ 07004



Facility Registration Number: 22-R-0069

The animals listed in Column E of APHIS Form 7023 included 223 guinea pigs, 12 hamsters and 156 rabbits. The rabbits and hamsters were used on irritation studies. These studies are used to determine the dermal, ocular or oral mucosa 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 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.

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

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

DEC 17 2001

| | | |
|---|---------------------|-----------------------------------|
| 1. REGISTRATION NO. 22-R-0082 | CUSTOMER NO. 190 | FORM APPROVED OMB NO 0579-0036 |
| 2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) PRODUCT SAFETY LABS., INC. 2394 ROUTE 130 DAYTON, NJ 08810 (732) 254-9200 | | |

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

FACILITY LOCATIONS(sites)

See Attached Listing

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|--|---|---|--|--|---|
| 4. Dogs | 0 | | | | |
| 5. Cats | 0 | | | | |
| 6. Guinea Pigs | 0 | 5340 | 6 | 170 | 5510 |
| 7. Hamsters | 0 | 76 | 0 | 0 | 76 |
| 8. Rabbits | 0 | 2085 | 23 | 201 | 2309 |
| 9. Non-Human Primates | 0 | | | | |
| 10. Sheep | 0 | | | | |
| 11. Pigs | 0 | | | | |
| 12. Other Farm Animals | 0 | | | | |
| 13. Other Animals | | | | | |
| Ferrets | 0 | 25 | 0 | 0 | 25 |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/26/01

RJW

ATTACHMENT TO USDA/APHIS ANNUAL REPORT OF RESEARCH FACILITY
EXPLANATION OF COLUMN "E" ENTRIES

191 Rabbits – Eye Irritation Test (OPPTS 870.2400): Eleven (11) 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 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.

6 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.

4 Rabbits – Acute Dermal Toxicity Test (OPPTS 870.1200): One animal sustained an accidental mechanical injury to the lumbar spine and/or hind limbs. The animal was humanely euthanized. Three rabbits vocalized during the removal of the the dermal wrapping which had reacted with the test article and become more sticky. These animals immediately became calm and were returned to their cages.

170 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.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0108 193 FORM APPROVED
OMB NO. 0579-0036

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

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,
include Zip Code)
EXXONMOBIL BIOMEDICAL SCIENCES, INC.
P.O. BOX 971
1545 ROUTE 22 EAST
ANNANDALE, NJ 08801-0971

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

FACILITY LOCATIONS(sites)

EXXONMOBIL BIOMEDICAL SCIENCES, INC.
ANNANDALE, NJ 08801-0971

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | 144 | | 30 | 174 |
| 7. Hamsters | | | | | |
| 8. Rabbits | | 101 | | 19 | 120 |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| : | | | | | |

ASSURANCE STATEMENTS

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

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

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

| SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) | DATE SIGNED |
|---|--|-------------|
| | | 11/26/2001 |

1. Registration Number: 22-R-0108 / 193

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

Guinea Pigs (30)

Rabbits (19)

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

Three study types were identified as potentially producing pain or distress in rabbits or guinea pigs at ExxonMobil Biomedical Sciences, Inc. (EMBSI) during the 2000 - 2001 APHIS census year. All three study types followed accepted regulatory or international test guidelines (OECD 404, 405 and 406) and were conducted for regulatory purposes. These study types and the related procedures are listed below: . Ocular Irritation Studies: Involved the administration of 0.1 ml or 0.1 grams of test substance into conjunctival sac of the rabbit eye. The rabbits were then observed daily until termination. . Dermal Irritation Studies: Involved the administration of 0.5 ml or 0.5 grams of test substance onto a 1" x 1" area of skin. The skin is exposed to the test substance for four hours under a semi-occluded dressing. The rabbits were then observed daily until termination. . Guinea Pig Sensitization Studies: Involved an intradermal injection of the test material in Freund's complete adjuvant to the clipped scapular area followed by a topical administration of the test material over the injection sites in an attempt to induce sensitization. All animals were topically challenged on a naive clipped site after a two-week rest period following the induction phase. The animals were observed daily and evaluated for dermal irritation 24 and 48 hours after all applications of the test substance. Because the measure of pain in animals can not always be determined with certainty, the criteria listed in Appendix A were used for determining pain or distress for rabbits or guinea pigs used for the above study types conducted at EMBSI. These criteria, revised in 1997, are consistent with the definition of "painful procedures" defined in 9CFR, Subchapter A, Animal Welfare, Part 1 as well as scientific literature on the subject. The revised criteria developed in 1997 were in response to specific comments made by USDA during a January 1997 inspection, and upon the review of our IACUC. Between October 1, 2000 and September 30, 2001, 49 animals met the criteria listed above and therefore considered possibly to have been in pain or distress. The following further categorizes these animals. . # of Animals Reason for possible pain or distress . 12 Rabbits

Severe eye irritation (e.g. conjunctival redness score . of "3", chemosis score greater than "2", and corneal dye retention indicative of ulceration)- Ocular Irritation Studies 5 Rabbits Irritation score of "4" - Dermal Irritation Studies 1 Rabbit Emaciation 1 Rabbit Died 19 Guinea Pigs

Irritation score of "3" or eschar - Guinea Pig . Sensitization Studies 11 Guinea Pigs

Emaciated - Guinea Pig Sensitization Studies . The observed irritation scores were related to the test procedures. The emaciated states and death were judged to be of natural causes, i.e., not related to treatment. None of the animals listed above were treated for pain or distress. However, the emaciated rabbit was given a saline water dish and the guinea pigs that were emaciated were given water dishes and moistened food. . Appendix A .

Signs of Pain and Distress . Clinical Signs . The following are considered clear signs of animals in pain or distress. Convulsions Coarse Tremors Dyspnea Respiratory Arrhythmia

Hyperpnea Hypopnea Wet rales Emaciation Hypothermia
Abdominal Gripping Prolapsed uterus Prolapsed rectum Teeth Grinding Dystocia

Ranting (other than Foot stomping (other than momentary (momentary) . Additionally, any animal that can not access its food or water will be considered an animal in pain or distress. . Dermal Irritation Erythema

score of 4 (Draize scale) Eschar Edema score greater than 2 (Draize scale) Necrosis Dermal irritation score of 3 (Buehler scale) Blanching (full depth) Dermal sore/ulceration Fissuring .

Ocular Irritation Conjunctival redness score of 3 Conjunctival ulceration Conjunctival chemosis score greater than 2 Iris score of 2 Corneal opacity score greater than 2 Conjunctival necrosis Blistering conjunctiva Ruptured eye Protruding cornea Pannus Corneal dye retention

Indicative of ulceration . The following are considered subjective signs of animals in pain or distress. The observation of any one of these signs would not be considered sufficient to consider an animal in pain or distress. However, the occurrence of these signs with other related clinical signs may be considered a sign of pain or distress. The Study Director will make the determination of whether an animal with these signs was in pain or distress. . Ataxia

Fine Tremors Piloerection Aggressive Ranting Foot stomping Teeth
chattering Vocalizing Abdominal Staining Cyanosis Unthrifty coat Small
amount of stool No stool Distended abdomen Food consumption Decrease Red ocular discharge

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)

The animals were not treated for pain or distress because the effects of anesthetic/analgesic agents on the study outcome were not known. In ocular irritation tests and dermal irritation tests, recovery is a key endpoint of the study.

Anesthetic/analgesic agents may affect this recovery process. In guinea pig sensitization tests, the animals must be observed for a designated period of time and in some instances be rechallenged to generate meaningful data. Also, in the ocular irritation and dermal irritation studies where the animals received only a single exposure, any pain or distress that may have occurred did not persist or progress, i.e., the responses observed in the studies were transient. The Study Directors for each of these study types were aware of the effects seen in the animals and monitored the animals' health.

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: Ocular Irritation Studies - OECD, Organization for CFR:
Economic Cooperation and Development, Guidelines for
Testing of Chemicals, Test Guideline 405, 1987; .; Dermal
Irritation Studies - OECD, Organization for Economic
Cooperation and Development, Guidelines for Testing of
Chemicals, Test Guideline 404, 1992; .; Guinea Pig
Sensitization Studies - OECD, Organization for Economic
Cooperation and Development, Guidelines for Testing of
Chemicals, Test Guideline 406, 1992

Approval Status:

Approved/Disapproved By:

Date:

Disapproved Reason:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. CUSTOMER NO.
22-R-0126 12286

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,
include Zip Code)
B A S F CORPORATION
P.O. BOX 400
PRINCETON, NJ 08543
(609) 716-2330

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

FACILITY LOCATIONS (sites)

See Attached Listing

Quakerbridge and Clarksville Roads

Princeton, New Jersey 08543

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|--|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | 19 | 17 | 0 | 12 | 29 |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

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

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

DATE SIGNED

9/24/01

USDA Annual Report - 2001
BASF Agro Research
Registration Number 22-R-0126

Explanation of Column E Entry

The 12 rabbits listed in Column E were used for ocular irritation studies. These studies were performed using the Guidelines published in the Federal Register, EPA Health Effects Guidelines, OPPTS 870.2400. The data provided by these studies is used to evaluate the toxic and irritant potential of novel proprietary compounds. This information is an integral part of the product submission packets provided to federal and foreign governmental agencies.

The concurrent administration of other chemicals, including analgesic and anesthetic compounds, to the test animals has the potential to mask or alter adverse signs. In addition, the administration of other chemicals might interact with the test articles. Either effect would interfere with the proper evaluation of the test results.

The criteria used to determine column E entry is based on the Draize¹ scoring system. Any animal in a primary eye irritation study that has a score of 2 or more for either corneal opacity or conjunctival irritation (redness or swelling, discharge is excluded) and/or an iris score of 1 at anytime during the course of the study are placed in column E.

These studies were reviewed and approved by the Institutional Animal Care and Use Committee.

¹ Draize, H.J., Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, Assoc. of Food and Drug Officials of the United States, 3rd Printing, 1975, page 51.

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

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0127 12287

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,
include Zip Code)
FT DODGE ANIMAL HEALTH
P O BOX 5366
PRINCETON, NJ 08543
(609) 716-2330

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

FACILITY LOCATIONS(sites)

See Attached Listing

Quakerbridge and Clarksville Roads

Princeton, New Jersey 08543

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. (Cols. C + D + E) |
|------------------------|---|---|--|--|-------------------------|
| 4. Dogs | | | | | |
| 5. Cats | | 24 | | | 24 |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | 0 | 6 | 0 | | 0 6 |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| Gerbils | 120 | 2473 | 0 | 44 | 2517 |
| | | | | | |
| | | | | | |

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

10/11/01

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

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT) 2001 RCVD

| | | |
|---|---------------------|------------------------------------|
| 1. REGISTRATION NO. 22-R-0006 | CUSTOMER NO. 169 | FORM APPROVED OMB NO. 0579-0036 |
| 2. HEADQUARTERS RESEARCH FACILITY (Type or Print) (Include Zip Code) Per ORTHO PHARMACEUTICAL CORPORATION P O BOX 300 ROUTE 202 RARITAN, NJ 08869 (908) 704-4285 | | |

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

FACILITY LOCATIONS/sites)

See Attached Listing

R.W. Johnson, PRI Raritan, NJ

R.W. Johnson, PRI Spring House, PA

R.W. Johnson, PRI, LaJolla, CA

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquillizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|---|---|--|--|--|---|
| 4. Dogs | - | *270 | *297 | 98 | 665 |
| 5. Cats | - | - | - | - | - |
| 6. Guinea Pigs | 2 | 50 | *618 | *304 | 972 |
| 7. Hamsters | - | - | - | - | - |
| 8. Rabbits | - | *219 | *147 | 47 | 413 |
| 9. Non-Human Primates | *20 | *43 | *30 | *14 | 87 |
| 10. Sheep | - | - | - | - | - |
| 11. Pigs | - | - | - | - | - |
| 12. Other Farm Animals | - | - | - | - | - |
| 13. Other Animals | | | | | |
| Chinchilla | 0 | 0 | 0 | 20 | 20 |

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

Q.C. JW

ATTACHMENT 1

USDA ANNUAL REPORT (2000-2001)

Registration #: 22-R- 0006

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

| SPECIES | CATEGORY B | CATEGORY C | CATEGORY D | CATEGORY E |
|--------------------|------------|------------|------------|------------|
| DOGS | 0 | 114 | 91 | 0 |
| GUINEA PIGS | 0 | 0 | 33 | 39 |
| RABBITS | 0 | 18 | 88 | 0 |
| NON-HUMAN PRIMATES | 5 | 43 | 30 | 14 |

USDA ANNUAL REPORT (2000-2001)**Registration #: 22-R- 0006****Animals Listed in Category E**

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

| SPECIES | NUMBER | PROCEDURE/JUSTIFICATION |
|--------------------|-----------------|-------------------------|
| Chinchillas | 20 | (b)(4) |
| Guinea Pigs | 199 80 25 | |
| Rabbits | 47 | |
| Dogs | 98 | |
| Non-Human Primates | 14 | |

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

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

RAB

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,

22-R-0050. Cust Id 520

SGS U.S. Testing Company Inc.
291 Fairfield Avenue
Fairfield, NJ 07004

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research if necessary)

ses. Attach additional

FACILITY LOCATIONS (Sites)

SGS U.S. Testing Co., Inc.

75 Passaic Ave., Fairfield, NJ 07004

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

| A. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which 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). | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report). | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|---|---|
| 4. Dogs | N/A | | | | |
| 5. Cats | N/A | | | | |
| 6. Guinea Pigs | 0 | 310 | 0 | 416 | 726 |
| 7. Hamsters | N/A | | | | |
| 8. Rabbits | 0 | 329 | 2 | 83 | 414 |
| 9. Non-human Primates | N/A | | | | |
| 10. Sheep | N/A | | | | |
| 11. Pigs | N/A | | | | |
| 12. Other Farm Animals | N/A | | | | |
| 13. Other Animals | N/A | | | | |

ASSURANCE STATEMENTS

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

BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Officer or Legally Responsible Institutional Official)
The above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF:

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

DATE SIGNED

11/29/01

88), which is obsolete.)



Registration #22-R-0050

COMMENTS, APHIS FORM 7023

- A. The 416 guinea pigs that experienced pain without benefit of analgesics or anesthetic during tests were used in the Kligman Skin Sensitization tests required for the compliance with the Federal Hazardous Substance Act Regulation, the Federal Insecticide, Fungicide and Rodenticide Act regulation and the Toxic Substance Control Act regulation. The concomitant use of analgesic, anesthetic or tranquilizing drugs in these procedures, according to these regulations, would have adversely affected the interpretation of the results.
- B. The 83 rabbits that experienced pain without benefit of general analgesics or anesthetics during tests were used in eye and primary skin irritation studies required for the compliance with the Federal Insecticide, Fungicide and Rodenticide Act regulation and the Toxic Substance Control Act regulation. The concomitant use of analgesic, anesthetic or tranquilizing drugs in these procedures, according to these regulations, would have adversely affected the interpretation of the results.

It is the policy of the Toxicology Laboratory to use the minimum number of animals necessary to ascertain hazards associated with chemical insult for any sample tested. The welfare of laboratory animals used in toxicologic studies is an integral part of our laboratory policy. Test substances are flushed from the eye or removed from the skin site as soon as possible without compromising the test protocol. Animals receive local anesthetics, topical antibiotics and the best care available post-testing if chemical insult is minor. The Study Director examines all animals involved in studies where a test article is rated a severe eye or skin irritant. Euthanasia by lethal injection of pentobarbital is performed if an animal is suffering.

- C. There were no IACUC-approved exception(s) to the regulations or standards.

By _____

11/29/01
Date

USDA Annual Report – 2001
Fort Dodge Animal Health
Registration Number 22-R-0127

The 44 gerbils reported in Category E were used in efficacy testing of novel compounds for *in vivo* anthelmintic activity. The test compounds were administered as a single oral dose. The gerbils were found dead during the routine morning morbidity and mortality check. Premonitory signs were not observed during the day before. Therefore, this finding was not anticipated. Because the interval between onset of signs, if any, and death could not be determined, an assumption has been made that these gerbils could have experienced more than transient pain or distress prior to death.

This protocol was reviewed and approved by the Institutional Animal Care and Use Committee.

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

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.
22-R-0121 1719

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT) 16-2001 RCV

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
MERIAL LIMITED
3239 SATELLITE BLVD., BLDG 500
DULUTH, GA 30096

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

FACILITY LOCATIONS(sites)

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. | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs 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) | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report) | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|------------------------|---|---|--|--|---|
| 4. Dogs | | 460 | 21 | | 481 |
| 5. Cats | | 236 | | 4 | 240 |
| 6. Guinea Pigs | | 152 | 86 | | 238 |
| 7. Hamsters | | 2765 | | 2365 | 5130 |
| 8. Rabbits | | 24 | 200 | | 224 |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| Ferrets | | 4 | | | 4 |

ASSURANCE STATEMENTS

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

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

Chief Executive Officer or Legally Responsible Institutional official

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

OFFICIAL

DATE SIGNED

Nov-14, 01

EG

Attachment A for APHIS form 7023

1.0 Column E, Line 5, Animal – Cats

- 1.1 Sixteen cats were used in a study for development of a product (b)(4)

(b)(4) The development studies for this compound require assessment of efficacy in the target animal species using a model of acute pain. In this study four cats experienced a painful situation for a time period of < 48 hours. The addition of other analgesics would interfere with the evaluation of this compound.

2.0 Column E, Line 7, Animal – Hamsters

- 2.1 Five thousand one hundred thirty hamsters were used in testing bacterin prior to release for sale as required by (b)(4). This testing requires challenging hamsters with the virulent agent in order to evaluate bacterin efficacy and potency. 2365 hamsters experienced weightloss, debilitation and/or death. Anesthetics, analgesics and tranquilizing drugs are not appropriate for this agent and would interfere with the evaluation of this bacterin.

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 22-R-0121
Customer Number: 1719
Facility: MERIAL LIMITED
3239 SATELLITE BLVD., BLDG 500
DULUTH, GA 30096

MERIAL
6498 JADE RD
FULTON, MO 65251

COLBERT, GA
JOHNNY MCELROY RD
COLBERT, GA 30628

ATHENS, GA
115 TRANSTECH DR
ATHENS, GA 30601