

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0005  
CUSTOMER NUMBER: 8203

FORM APPROVED  
OMB NO. 0579-0036

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

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

OCT 01 2004

Telephone: (609)-292-5847

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

Lab Bldg.-PH&EL

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

**ASSURANCE STATEMENTS**

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

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

SIGNATURE O

DATE SIGNED

9/23/07

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0012  
CUSTOMER NUMBER: 172

FORM APPROVED  
OMB NO. 0579-0036

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

Ethicon, Inc.  
Ethicon Research Foundation  
P.O. Box 151  
Somerville, NJ 08876

NOV 24 2004

Telephone: ~~(908) 218-2884~~ (908) 218-2894

**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)

ETHICON, INC.  
P.O. BOX 151  
SOMERVILLE, NJ 08876

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 animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs			16		16
5. Cats					
6. Guinea Pigs			207		207
7. Hamsters			32		32
8. Rabbits			112		112
9. Non-human Primates					
10. Sheep					
11. Pigs			495		495
12. Other Farm Animals					
Goats			3		3
13. Other Animals					

**ASSURANCE STATEMENTS**

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

DATE SIGNED

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0013  
CUSTOMER NUMBER: 163

FORM APPROVED  
OMB NO. 0579-0036

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

Worldwide Mobile Veterinary Unit  
8 Foxhunt Drive  
Rockaway, NJ 07866  
  
Telephone: (973)-361-5428

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs			10		10
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 rese teaching, testing, surgery, or experimentation were followed by this research facility.
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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
( Chief Executive Officer or Legally Responsible Institutional Official )

Print ) \_\_\_\_\_ DATE SIGNED  
*11/26/04*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

NOV 24 2004

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		30			30
9. Non-human Primates					
10. Sheep					
11. Pigs		17	4		21
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 res teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

NOV 09 2004

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely effected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas: such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs			72		72
5. Cats			6		6
6. Guinea Pigs		7			7
7. Hamsters		3	50		53
8. Rabbits	13	1	121		135
9. Non-human Primates					
10. Sheep					
11. Pigs			122		122
12. Other Farm Animals					
13. Other Animals					
Woodchucks			8		8

**ASSURANCE STATEMENTS**

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

DATE SIGNED  
*10/27/04*

NOV 30 2004

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

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

FACILITY LOCATIONS ( Sites ) - See 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 animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats			11		11
6. Guinea Pigs			27		27
7. Hamsters					
8. Rabbits			20		20
9. Non-human Primates			20		20
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Marmosets		59			59

**ASSURANCE STATEMENTS**

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

( Print )

DATE SIGNED

11-29-04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

DEC 01 2004

Telephone: (732) -932-0150

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

FACILITY LOCATIONS ( Sites ) - See 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 animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	11	12	50		62
5. Cats			41		41
6. Guinea Pigs		91	554		645
7. Hamsters		100			100
8. Rabbits	MES 9 7		MES 20 16		MES 20 16
9. Non-human Primates			5		5
10. Sheep					
11. Pigs			9		9
12. Other Farm Animals					
DEER MICE		35			35
13. Other Animals					
GERBILS	18	64			64
DEER		15			15
HEDGEHOG		1			1

**ASSURANCE STATEMENTS**

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

DATE SIGNED

11-30-04

Customer ID and Site Address:

ID: 177

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

Telephone

Customer ID and Site Address:

ID: 177

197 University Avenue  
Newark, NJ 07102  
County: Essex

Telephone

Customer ID and Site Address:

ID: 177

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

Telephone

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)  Lawrenceville, NJ / A#1	1. CERTIFICATE NUMBER: 22-R-0028 CUSTOMER NUMBER: 168	FORM APPROVED OMB NO. 0579-0036
Bristol Myers Squibb Company <b>NOV 23 2004</b> P.O. Box 4000, D24-01 Princeton, NJ 08543  Telephone: (609) -252-4870		

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	5	22	57	4	83
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	1	4	0	5
7. Hamsters	0	13	193	0	206
8. Rabbits	5	0	0	0	0
9. Non-human Primates	0	24	56	0	80
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

**ASSURANCE STATEMENTS**

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HEADQUARTERS RESEARCH FACILITY OFFICIAL (Principal Investigator or Legally Responsible Institutional Official)		
SIGNATURE OF C.E.O. OR INSTITUTITIC	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	DATE SIGNED <b>11/16/04</b>

*Ward*

## 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-028
2. Number: 7 of animals used in this study.
3. Species (common name): Beagle Dog of animals used in this study.

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

**Two dogs** experienced adverse events during an oral pharmacokinetics study. The momentary pain and/or distress was due to an oral dosing accident, it was not part of the study design. As soon as pain/distress was observed (lethargy, rapid, shallow breathing, pale mucous membrane color), the animals were immediately 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 Item 6 below).

The pain/distress experienced by the dogs was not part of the study design, but a by-product of an oral dosing accident. The procedure itself, when performed correctly is not painful or distressful. The pain/distress was alleviated by immediate euthanasia.

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

Agency \_\_\_\_\_ CFR \_\_\_\_\_

## 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-028
2. Number: 20 of animals used in this study.
3. Species (common name): Beagle (Dog) of animals used in this study.
4. Explain the procedure producing pain and/or distress:

**Two dogs** used in a single-oral dose toxicity study experienced pronounced cardiovascular effects (bradycardia, sinoatrial arrest and accompanying arrhythmia).

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).

Supportive measures by qualified veterinary staff including medication to return and maintain sinus rhythm were undertaken. However, the use of anesthetic, analgesic, or tranquilizing agents was not possible because of their potential interference with the understanding of the toxicity profile of the pharmaceutical candidate being tested. This study was conducted as part of a series of evaluations leading to potential further pharmaceutical development in humans and the conduct was consistent with expectations of international regulatory authority guidelines.

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):

Guidance for industry. M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals. International Conference on Harmonization (ICH) 1997.

Agency: Federal Register, Vol. 62, November 25, 1997, Page 62922, Docket No. 97D-0147  
CFR: 62 CFR

**Appendix #1**

**7023 Forms for  
22-R-0028**

**October 1, 2003 - through September 30, 2004**

**Attachments**

**A #1, #2, #3, #4**

**B**

**C**

**D**

Pages - series A-D

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )  New Brunswick, NJ / A#2	1. CERTIFICATE NUMBER: 22-R-0028 CUSTOMER NUMBER: 168	FORM APPROVED OMB NO. 0579-0036  <b>NOV 23 2004</b>
Bristol Myers Squibb Company P.O. Box 4000, D24-01 Princeton, NJ 08543  Telephone: (609)-252-4820		

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	70	319	47	0	366
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	331	57	3	391
9. Non-human Primates	40	34	0	3	37
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

**ASSURANCE STATEMENTS**

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

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

SIGNATURE	OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED <i>11/16/04</i>
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*SPCEN*

### Column E Explanation

This form is intended as a 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-0028**
2. Number: **43** of animals used in this study.
3. Species (common name): **Rabbits** of animals used in studies.
4. Explain the procedure producing pain and /or distress.

The **3 Rabbits** included in column "E" were used in routine toxicity studies of new pharmaceutical compounds. New pharmaceutical compounds administered by the **Oral** route(s) elicited a range of side effects attributed to compound administration.

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)

These studies were conducted as part of a series of tests leading to potential further drug development in humans. *Oral* toxicity tests were performed in compliance with Good Laboratory Practice Regulations of the Food and Drug Administration (FDA). The use of anesthetic, analgesic, or tranquilizing agents was not possible in any of these studies because of their potential interference with the toxicity profile of the new pharmaceutical compounds being tested.

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):

FDA: Guidance For Industry M3 Nonclinical Safety Studies For The Conduct Of Human Clinical Trials For Pharmaceuticals. Federal Register, Vol. 62, November 25, 1997, page 62922, Docket No. 97D-0147.

### Column E Explanation

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1. Registration Number: **22-R-0028**
2. Number: 6 of animals used in this study.
3. Species (common name): **Monkeys (Cynomolgus)** of animals used in studies.
4. Explain the procedure producing pain and /or distress.

The **3 Monkeys** included in column "E" were used in routine toxicity studies of new pharmaceutical compounds. New pharmaceutical compounds administered by the **Oral** route(s) elicited a range of side effects attributed to compound administration.

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)

These studies were conducted as part of a series of tests leading to potential further drug development in humans. *Oral* toxicity tests were performed in compliance with Good Laboratory Practice Regulations of the Food and Drug Administration (FDA). The use of anesthetic, analgesic, or tranquilizing agents was not possible in any of these studies because of their potential interference with the toxicity profile of the new pharmaceutical compounds being tested.

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FDA: Guidance For Industry M3 Nonclinical Safety Studies For The Conduct Of Human Clinical Trials For Pharmaceuticals, Federal Register, Vol. 62, November 25, 1997, page 62922, Docket No. 97D-0147.

The New Brunswick ACUC – approved exceptions to the dog exercise plan for environmental enhancement also occurred between October 1, 2003, and September 30, 2004. Our dogs are given the opportunity for routine self-exercise in spacious indoor-outdoor runs. During the USDA accounting for research use, October 1, 2003, to September 30, 2004 approximately 212 of the dogs listed in column C on our Form 7023 spent one to three separate twenty four hour periods (depending on the length of the study) in housing cages designed to collect urine metabolites. These urine collections are a required step in FDA/GLP required study conduct under CFR 21 58.3. Due to the critical nature of obtaining proper study data from the urinary output, the New Brunswick IACUC approved the suspension of the dog exercise program for scientific reasons during the period in which urine is collected. After urine collection is complete the dogs are immediately returned to their housing runs and again given the opportunity for daily self-exercise.

The New Brunswick ACUC approved exceptions to the pair housing for nonhuman primates plan for environmental enrichment also occurred between October 1, 2003 and September 30, 2004. All primates are pair or group housed in New Brunswick and when this is not possible arrangements are made to provide additional environmental enrichment. During the USDA accounting for research use, October 1, 2003 to September 30, 2004 approximately 2 of the nonhuman primates listed in column C on our form 7023 spent 30 days individually housed. Due to the critical nature of obtaining proper study data from these animals the New Brunswick ACUC approved suspension of our pair/group housing program for scientific reasons.

Sincerely,

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

A large black rectangular redaction box covers the signature area, obscuring the name and any handwritten notes or dates that might have been present.

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )  Somerville, NJ / A#3	1. CERTIFICATE NUMBER: 22-R-0028 CUSTOMER NUMBER: 168	FORM APPROVED OMB NO. 0579-0036  <b>NOV 23 2004</b>
Bristol Myers Squibb Company P.O. Box 4000, D24-01 Princeton, NJ 08543  Telephone: (609)-252-4820		

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reaso such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates	386				
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 rest teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

SIGNATURE OF C.	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	DATE SIGNED <i>11/16/14</i>
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*11/16/14*

## **Exemption to allow pair housing of animals up to 3.5 kg each**

Somerville requested an IACUC exemption to our housing program, allowing us to pair house our animals, 2 per cage, up to 3.5 kg each. Additionally, we requested an exemption to house 3 animals in 2 cages, using a tunnel to connect the caging. The animals housed in such a configuration could weigh up to 4.5 kg each.

The Animal Welfare Act regulations and the Guide for the Care and Use of Laboratory Animals guidelines state that the recommended space for our animals is:

- Up to 1 kg      1.6 sq. ft.
- Up to 3 kg      3.0 sq. ft.
- Up to 10 kg     4.3 sq. ft.

The square footage of the Somerville cage is 6.3 sq. ft.

### **Justification for this exemption:**

The animals are pair housed when they arrive at Somerville and we try to keep the pairing for enrichment purposes throughout their stay in Somerville. The animals do well with their paired mate and to break up the pair or add another animal to the mix simply to meet guidelines does not seem to take the best welfare of the animal into account.

The guide states, "Whenever it is appropriate, social animals should be housed in pairs...". "Recommendations ... are based on the assumption that pair or group housing is generally preferable to single housing, even when members of the pair or group have slightly less space per animals than when singly caged. For example, each animal can share the space allotted to the animals with which it is housed." "Some species of nonhuman primates use vertical dimensions of the cage to a greater extent than the floor. For them, the ability to perch and to have adequate vertical space to keep the whole body above the cage floor can improve their well-being."

The Act states that "Innovative primary enclosures not precisely meeting the floor area and height requirements ..... but that do provide nonhuman primates with sufficient volume of space and the opportunity to express species-typical behavior, may be used in research facilities when approved by the Committee...."

The Committee discussed this request, and the only concern we expressed related to the need to separate animals. The exemption addresses this concern with the following statement: "Animals that cannot be pair housed or triple housed due to incompatibility or as a result of fighting, illness or other reasons would be housed either singly or in a different configuration of animals."

The Committee unanimously approved this request on June 24, 2004.

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0028  
CUSTOMER NUMBER: 168

FORM APPROVED  
OMB NO. 0579-0036

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

Wallingford, CT / B

Bristol Myers Squibb Company  
P.O. Box 4000, D24-01  
Princeton, NJ 08543

NOV 23 2004

Telephone: (609)-252-4820

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasr such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	12	16	41		57
5. Cats	0	0	0		0
6. Guinea Pigs	0	57	0		57
7. Hamsters	0	23	0		23
8. Rabbits	9	0	40		40
9. Non-human Primates	18	8	43		51
10. Sheep	0	0	0		0
11. Pigs	0	0	0		0
12. Other Farm Animals					
13. Other Animals					
<b>Gerbils</b>	<b>423</b>	<b>860</b>	<b>674</b>	<b>1369</b>	<b>2903</b>

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

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

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

DATE SIGNED

11/16/04

*Handwritten signature/initials*

## 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-028
2. Number 1369 of animals used in this study.
3. Species (common name) gerbil of animals used in the study.
4. Explain the procedure producing pain and/or distress.

**One thousand three hundred sixty-nine** gerbils were used in a study to assess the therapeutic efficacy of antidepressant and anxiolytic compounds. Gerbils were dosed with test compounds either orally or parenterally. Fifteen to sixty minutes after dosing, the gerbils were placed individually into a 30 cm high, 50 cm diameter glass container filled with 22 – 26° C water to a level of 22 cm. For a period of 6 minutes the gerbil's swimming behaviors which our ACUC wants to classify as distressful were evaluated and measured (ex. Immobility, climbing, swimming). Subjects were closely monitored during the study. At the conclusion of the study gerbils were euthanatized with carbon dioxide.

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 use of analgesics or anesthetics to relieve the distress associated with this procedure would interfere with assessment of novel compounds for the treatment of anxiety and depression. This behavioral paradigm is used to detect potential antidepressants and anxiolytics which produce their pharmacological effects through similar mechanisms of action as the analgesics and anesthetics.

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

Agency \_\_\_\_\_ CFR \_\_\_\_\_

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)  (East) Syracuse, NY / C	1. CERTIFICATE NUMBER: 22-R-0028 CUSTOMER NUMBER: 168	FORM APPROVED OMB NO. 0579-0038
Bristol Myers Squibb Company P.O. Box 4000, D24-01 Princeton, NJ 08543  Telephone: (609)-252-4820		NOV 23 2004

**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

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4. Dogs	73	145	0	2	147
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	9	3	0	0	3
9. Non-human Primates	58	222	28	5	255
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

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( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE	FICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	DATE SIGNED
			11/16/04

[Handwritten Signature]

Special Use:

## Column E Explanation

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1. Registration Number: **22-R-0028**
2. Number: **34** of animals used in this study.
3. Species (common name): **Beagle (Dog)**
4. Explain the procedure producing pain and/or distress.

The 1 dog used in a routine toxicity study of pharmaceutical compounds at this site was included in Column E. New pharmaceutical compounds were administered to these animals by the oral route. Some compound administered by this route elicited adverse side effects, which led to inclusion of these animals in "Column E".

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)

These studies were conducted as part of a series of tests leading to potential further drug development in humans. Oral toxicity tests were performed in compliance with Good Laboratory Practice Regulations of the Food and Drug Administration (FDA). The use of anesthetic, analgesic, or tranquilizing agents was not possible in any of these studies because of their potential interference with the toxicity profile of the new pharmaceutical compounds being tested.

### Summary of Exemptions:

A total of 39 dogs on 4 separate toxicity studies were exempted from exercise during the reporting period. This was done for personnel safety reasons due to the characteristics of the compounds being tested. There were no other exceptions to USDA standards and regulations that applied to dogs during the reporting period.

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):

FDA: Guidance For Industry M3 nonclinical Safety Studies For The Conduct Of Human Clinical Trials For Pharmaceuticals, Federal Register, Vol. 62, November 25, 1997, page 62922, Docket No. 97D-0147.

Special Use:

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1. Registration Number: **22-R-0028**
2. Number: **11** of animals used in this study.
3. Species (common name): **Beagle (Dog)**
4. Explain the procedure producing pain and/or distress.

The 1 dog used in a routine toxicity study of pharmaceutical compounds at this site was included in Column E. New pharmaceutical compounds were administered to these animals by the oral route. Some compound administered by this route elicited adverse side effects, which led to inclusion of these animals in "Column E".

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)

These studies were conducted as part of a series of tests leading to potential further drug development in humans. Oral toxicity tests were performed in compliance with Good Laboratory Practice Regulations of the Food and Drug Administration (FDA). The use of anesthetic, analgesic, or tranquilizing agents was not possible in any of these studies because of their potential interference with the toxicity profile of the new pharmaceutical compounds being tested.

### Summary of Exemptions:

A total of 39 dogs on 4 separate toxicity studies were exempted from exercise during the reporting period. This was done for personnel safety reasons due to the characteristics of the compounds being tested. There were no other exceptions to USDA standards and regulations that applied to dogs during the reporting period.

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Special Use:

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1. Registration Number: **22-R-0028**
2. Number: **16** of animals used in this study.
3. Species (common name): **Nonhuman primates**
4. Explain the procedure producing pain and/or distress.

The **five** nonhuman primates used in a routine toxicity study of pharmaceutical compounds at this site was included in Column E. New pharmaceutical compounds were administered to these animals by the oral route. Some compound administered by this route elicited adverse side effects, which led to inclusion of these animals in "Column E".

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)

These studies were conducted as part of a series of tests leading to potential further drug development in humans. Oral toxicity tests were performed in compliance with Good Laboratory Practice Regulations of the Food and Drug Administration (FDA). The use of anesthetic, analgesic, or tranquilizing agents was not possible in any of these studies because of their potential interference with the toxicity profile of the new pharmaceutical compounds being tested.

Summary of Exemptions:

No exemptions to USDA standards and regulations applied to nonhuman primates during the reporting period.

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):

FDA: Guidance For Industry M3 nonclinical Safety Studies For The Conduct Of Human Clinical Trials For Pharmaceuticals, Federal Register, Vol. 62, November 25, 1997, page 62922, Docket No. 97D-0147.

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0028  
CUSTOMER NUMBER: 168

FORM APPROVED  
OMB NO. 0579-0036

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

Mount Vernon (Evansville), IN / D

Bristol Myers Squibb Company  
P.O. Box 4000, D24-01  
Princeton, NJ 08543

NOV 23 2004

Telephone: (609)-252-4820

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranqulliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	55	57	63	0	120
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	21	18	51	0	69
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

**ASSURANCE STATEMENTS**

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

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

SIGNATURE OF

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

DATE SIGNED

11/16/04

*[Handwritten signature]*

Supplement to the 2004 USDA Annual Report, APHIS Form 7023

Explanation of ACUC Approved Exception to a USDA Standard

2-R-0028: Bristol-Myers Squibb Company, Mount Vernon (Evansville) Indiana

The Evansville/ Mount Vernon ACUC has approved the following exception to USDA standards:

For enrichment purposes, purpose bred beagles are pair housed (study permitting) in runs 71" x 58" or larger. Larger runs are available for larger groups of dogs. In all cases at all times, the group housed dogs have at least the minimum amount of floor space required by USDA in their primary enclosure.

For 1-3 hours each day during dosing and feeding of the dogs and during cleaning of the runs, the beagles are placed in cages 22" x 16<sup>3</sup>/<sub>8</sub>" x 20<sup>3</sup>/<sub>8</sub>" or larger. The dogs are fed individually in these cages so as to give each dog equal access to the diet. The temporary, separate housing also allows technicians to work with each animal on a one on one basis, collecting individual clinical observations and minimizing distress during dosing.

Moving the dogs to the feeding/dosing cages while cleaning the runs helps maintain compliance with 3.11(a): "When steam or water is used to clean the primary enclosure, whether by hosing, flushing, or other methods, dogs and cats must be removed, unless the enclosure is large enough to ensure the animals would not be harmed, wetted, or distressed in the process." The use of the feeding/dosing cages minimizes the time that the dogs' paws are in contact with wet surfaces and thereby minimizes the incidence of interdigital dermatitis.

This exception was approved and in place for all dogs listed on form 7023.

**Appendix #2**

**Location of Bristol-Myers Squibb**

**Research Facilities**

**APPENDIX #2**

**Location of BMS - Research Facilities**

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, G2 and G2B  
Floor/Room: NA

Contact Person: (b)(6), (b)(7)(C)

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

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

Contact Person: (b)(6), (b)(7)(C)

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

Building: NA  
Floor/Room: NA

Contact Person: (b)(6), (b)(7)(C)

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

Building: 17  
Floor/Room: NA

Contact Person: (b)(6), (b)(7)(C)

**APPENDIX #2 (continued)**

**Location of BMS - Research Facilities**

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  
Wallingford, CT 06492-7660  
Building: Vivarium  
Floor/Room: N/A

Contact Person: (b)(6), (b)(7)(C)

***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: (b)(6), (b)(7)(C)

***D. Indiana***

Name/Department: Bristol-Myers Squibb Company  
Address: 2400 W. Lloyd Expressway  
Building: 101  
Floor/Room: N/A

Contact Person: (b)(6), (b)(7)(C)

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0028  
CUSTOMER NUMBER: 168

FORM APPROVED  
OMB NO. 0579-0036

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

Hopewell (Pennington), NJ / A#4

Bristol Myers Squibb Company  
P.O. Box 4000, D24-01  
Princeton, NJ 08543

Telephone: (609)-252-4820

NOV 23 2004

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasr such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs		22	42		64
5. Cats					0
6. Guinea Pigs		26	234		260
7. Hamsters		3331	17		3348
8. Rabbits			2494		2494
9. Non-human Primates			13		13
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 rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

SIGNATUR

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

DATE SIGNED

11/16/04

APHIS FORM  
( AUG 91 )

(OCT 88), which is obsolete.)

972

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

Merck & Company Inc  
126 E Lincoln Avenue  
Po Box 2000 RY80B-100  
Rahway, NJ 07065

NOV 23 2004

Telephone: 215-652-4890

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 reason such drugs were not used must be attached to this report )	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	223	877	1076	8	1961
5. Cats	34	10	0	0	10
6. Guinea Pigs	62	2053	732	0	2785
7. Hamsters	0	85	0	0	85
8. Rabbits	21	1234	1346	56	2636
9. Non-human Primates	3545	172	1086	0	1258
10. Sheep	0	0	0	0	0
11. Pigs	0	0	6	0	6
12. Other Farm Animals					
Horses	1	1	3	0	4
13. Other Animals					
Ferrets	24	44	48	18	110
Gerbils	0	5	0	0	5

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under 9 CFR 2.270 which require that exceptions to the standards and regulations be submitted and approved by the animal care and use committee (ACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the ACUC-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 )

SIGNATURE	INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
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APHIS FORM 7023A (AUG 91)

US FORM 18-23 (OCT 88) which is obsolete.

**USDA Annual Report: October 1, 2003 to September 30, 2004**

Merck & Co., Inc., Registration Number 22-R-0030, Customer Number 178  
770 Sumneytown Pike, WP 44-204, West Point, PA 19486 (215.652.4890)

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

126 E. Lincoln Avenue  
Rahway, NJ 07065-4607  
County: Union

Telephone: 732.594.6066

WP 44-204  
West Point, PA 19486-0004  
County: Montgomery

Telephone: 215.652.4890

WP 74-1  
West Point, PA 19486-0004  
County: Montgomery

Telephone: 215.652.6093

P. O. Box 016960 (R289)  
Miami, FL 33136  
County: Dade

Telephone: 305.243.8912 (Inactivated April 16, 2003)

20256 SW 360<sup>th</sup> Street  
Homestead, FL 33034-4102  
County: Dade

Telephone: 305.245.1551

P. O. Box 549  
Alice, TX 78333  
County: Jim Wells

Telephone: 361.664.4984 (Inactivated April 16, 2003)

4401 W. Admiral Doyle Drive  
New Iberia, LA 70560  
County: Iberia

Telephone: 337.482.0250 (Inactivated April 16, 2003)

**USDA Annual Report: October 1, 2003 – September 30, 2004**

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

**EXPLANATION OF ITEMS IN COLUMN E:**

1. Fifty six rabbits were on an IACUC approved protocol to evaluate the efficacy of new antibacterial compounds. The animals were infected with virulent bacteria and then treated with novel antibacterial compounds. Established antibacterial compounds could not be used to treat the animals' infections because they would interfere with the interpretation of the test result and defeat the purpose of the research. In addition, the interaction of pain-relieving agents with the novel compounds is unknown at this time. The total number of rabbits was kept to the minimum required to produce meaningful and reliable test results. Additionally, the length of the study was limited to the time necessary to establish the model and conduct the studies.
2. Eighteen ferrets were studied according to an IACUC approved protocol for assessing anti-emetic compounds. Intermittent nausea and vomiting were induced by the administration of an emetogen. Commercially available analgesics could not be administered because they would have confounded interpretation of data and defeated the purpose of the research. The minimum number of animals was used to provide reliable data and the length of the study was limited to eight hours or less. The animals were observed continuously during this period. Any animal that developed unusually severe (constant) emesis was euthanized immediately.
3. Eight dogs were studied according to an IACUC approved protocol for assessing histological changes in the central nervous system associated with hypoglycemia. Hypoglycemia was induced by the administration of a hypoglycemic agent. Treatment could not be administered because it would have confounded interpretation of data and defeated the purpose of the research. The minimum number of animals was used to provide reliable data. The period of time where animals experienced clinical signs due to hypoglycemia was limited to seven hours, which was the minimum duration needed to collect reliable data. The animals were immediately euthanized after this period. The animals were observed regularly during the study by the laboratory animal veterinarians and the investigative staff.

**USDA Annual Report: October 1, 2003 – September 30, 2004**

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

**IACUC Approved Exceptions to the Regulations:**

Exemption from the approved dog exercise plan was required on forty five occasions for a five-day urine/feces collection period after radioactive isotopes were administered.

Exemption from the approved dog exercise plan was required on two occasions for a six-day urine/feces collection period after radioactive isotopes were administered.

Exemption from the approved dog exercise plan was required on four occasions for a seven-day urine/feces collection period after radioactive isotopes were administered.

Exemption from the approved dog exercise plan was required on two occasions for an eight-day urine/feces collection period after radioactive isotopes were administered.

Exemption from the approved dog exercise plan was required on eleven occasions for a ten-day urine/feces collection period after radioactive isotopes were administered.

Exemption from the approved dog exercise plan was required on four occasions for a fourteen-day urine/feces collection period after radioactive isotopes were administered.

Three compatible female cynomolgus macaques were housed in a space less than that required by the USDA regulations as dictated by study and sanitation requirements. They were housed in this space for 57 days. No adverse effects were noted in the animals.

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	8		40		40
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs			2		2
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
		11/08/2004

DEC 02 2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0032  
CUSTOMER NUMBER: 180

FORM APPROVED  
OMB NO. 0579-0036

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

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

Telephone: (973) -235-5000

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

FACILITY LOCATIONS ( Sites ) - See 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 animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	26	225	24	4	253
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	3	90	0	93
7. Hamsters	0	0	0	0	0
8. Rabbits	0	68	0	1	69
9. Non-human Primates	22	26	40	1	67
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, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/29/04

## 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 2 of animals used in this study.
3. Species (common name) Nonhuman primate of animals used in the study.
4. Explain the procedure producing pain and/or distress.

One nonhuman primate in this study used to evaluate an anti-asthmatic compound was identified as a Category E. During the study, this animal presented with clinical signs of respiratory distress. Supportive care was administered by veterinary and research personnel.

The study was designed and conducted in accordance with the Food and Drug Administration guidelines.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)
6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR 58.1

## 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 50 of animals used in this study.

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

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

One pregnant rabbit in this study used to evaluate an anti-inflammatory compound aborted after drug administration.

Veterinary personnel observed all study animals daily and provided supportive care when needed.

The study was designed and conducted in accordance with the Food and Drug Administration guidelines.

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

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

Agency FDA CFR 58.1

### 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 40 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.

A total of 4 dogs from a group used to evaluate drug candidates for clinical trials were identified as Category E. These dogs were given a glucose lowering drug for the treatment of diabetes. During the study, the dogs presented with clinical signs of lethargy, ataxia, emesis and seizures.

Veterinary personnel observed all animal daily and supportive care included nutritional supplements and fluids.

The study was designed and conducted in accordance with the Food and Drug Administration guidelines.

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

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

Agency FDA CFR 58.1

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 22-R-0032 CUSTOMER NUMBER: 180	FORM APPROVED OMB NO. 0579-0036
Hoffmann-La Roche, Inc. Research & Development Div. 340 Kingsland Street Nutley, NJ 07110  Telephone: (973)-235-5000		

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

FACILITY LOCATIONS ( Sites ) - See 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 animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	26	225	24	4	253
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	3	90	0	93
7. Hamsters	0	0	0	0	0
8. Rabbits	0	68	0	1	69
9. Non-human Primates	22	26	40	1	67
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 rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ( Chief Executive Officer or Legally Responsible Institutional Official )		
S	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	DATE SIGNED 11/29/04

## 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 40 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.

A total of 4 dogs from a group used to evaluate drug candidates for clinical trials were identified as Category E. These dogs were given a glucose lowering drug for the treatment of diabetes. During the study, the dogs presented with clinical signs of lethargy, ataxia, emesis and seizures.

Veterinary personnel observed all animal daily and supportive care included nutritional supplements and fluids.

The study was designed and conducted in accordance with the Food and Drug Administration guidelines.

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

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

Agency FDA CFR 58.1

### 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 2 of animals used in this study.

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

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

One nonhuman primate in this study used to evaluate an anti-asthmatic compound was identified as a Category E. During the study, this animal presented with clinical signs of respiratory distress. Supportive care was administered by veterinary and research personnel.

The study was designed and conducted in accordance with the Food and Drug Administration guidelines.

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 Regulation's (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR 58.1

## 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 50 of animals used in this study.

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

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

One pregnant rabbit in this study used to evaluate an anti-inflammatory compound aborted after drug administration.

Veterinary personnel observed all study animals daily and provided supportive care when needed.

The study was designed and conducted in accordance with the Food and Drug Administration guidelines.

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

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

Agency FDA CFR 58.1

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0037  
CUSTOMER NUMBER: 752

FORM APPROVED  
OMB NO. 0579-0036

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

Rider University  
2083 Lawrenceville Road  
Lawrenceville, NJ 08648

NOV 26 2004

Telephone: (609) -896-5010

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

FACILITY LOCATIONS (Sites) - See Attached Listing *Science + Technology Building*

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not 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 tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits					0
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					
<i>A. cahirinus (spiny mice)</i>	300	20	0	0	320

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

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

DATE SIGNED

11/23/04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

Telephone: (609) -514-2524

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 reason such drugs were not used must be attached to this report )	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals			(Only rats and mice bred for research used)		

**ASSURANCE STATEMENTS**

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

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

SIGN

OFFICIAL ( Type or Print )

DATE SIGNED

10/14/21

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

Huntingdon Life Sciences, Inc.  
P.O. Box 2360  
East Millstone, NJ 08875  
  
Telephone: (732) -873-2550

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

FACILITY LOCATIONS ( Sites ) - See 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 animal 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, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	8	383	38	8	429
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	282	23	0	305
9. Non-human Primates	83	391	94	6	491
10. Sheep					
11. Pigs	0	88	3	5	96
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 rest teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary int brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	DATE SIGNED 11/15/04
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APHIS Form 7023 (OCT 88), which is obsolete.)

EG

**Annual Report of Research Facility  
October 1, 2003 to September 30, 2004  
Huntingdon Life Sciences  
Registration Number 22-R-0040**

**A) Explanation of Category E Studies**

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

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

<b>Species</b>	<b>Number of Category E Animals</b>	<b>Description</b>
Dogs	2	Animals were exposed to test compound via subcutaneous injection, intermittently over a 13 week period. Test article effects were evident in 2 animals. Consequently, these animals were humanely euthanized.
Dogs	6	Animals were exposed to test compound via oral gavage for three months. Test article effects were evident in 6 animals. Consequently, these animals were humanely euthanized.
Primate	6	Animals were exposed to test compound via intravenous injection. Test article effects were evident in 6 animals. Consequently, these animals were humanely euthanized.
Swine	5	Animals were exposed to test compound via dermal administration for approximately 28 days. Test article effects were evident in 5 animals. Dosing was discontinued in the affected animals.

**Annual Report of Research Facility  
October 1, 2003 to September 30, 2004  
Huntingdon Life Sciences  
Registration Number 22-R-0040**

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

- 14 dogs were exempted from the exercise requirement for 21 days during surgical recovery for implantation of a subcutaneous telemetry implant.
- 10 dogs were exempted from the exercise requirement for 5 days during surgical recovery for implantation of a subcutaneous telemetry implant.
- 8 dogs were exempted from the exercise requirement for 2 days due to data collection via subcutaneous telemetry implant.
- 8 dogs were exempted from the exercise requirement for 8 days due to data collection via subcutaneous telemetry implant.

OCT 18 2004

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

See attached form for additional information.

Interagency Report Control No.:

*ga*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0041  
CUSTOMER NUMBER: 173

FORM APPROVED  
OMB NO. 0579-0036

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

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

Telephone: (201)-847-6800

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasi such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0				
5. Cats	0				
6. Guinea Pigs	105	1610			1610
7. Hamsters	0				
8. Rabbits	12	389	51		440
9. Non-human Primates	0				
10. Sheep	0				
11. Pigs	0		143		143
12. Other Farm Animals	0				
13. Other Animals	0				

**ASSURANCE STATEMENTS**

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

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

DATE SIGNED

12 Oct 04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0050  
CUSTOMER NUMBER: 520

FORM APPROVED  
OMB NO. 0579-0036

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

S G S, U.S. Testing Company, Inc.  
291 Fairfield Avenue  
Fairfield, NJ 07004  
  
Telephone: (973) -575-5252

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report ).	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs	0	314	0	10	324
7. Hamsters					
8. Rabbits	0	271	0	77	348
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 reat teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inx brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

SIGNATURE	TITLE	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	DATE SIGNED 11/29/04
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APHIS FORM 7023 (OCT 88), which is obsolete. ( AUG 05 )

## COMMENTS, APHIS FORM 7023

- A. The 10 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 77 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:

11/29/04  
Date

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

*NOV 01 2004*

Telephone: (908) -218-8177

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	117	417	0	534
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Goats	11	6	0	0	6
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 res teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

DATE SIGNED

*10/28/04*

## APHIS Form 7023A Site List

The following sites have been reported by the facility:

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Registration Number:	22-R-0064
Customer Number:	182
Facility:	Ortho-Clinical Diagnostics, Inc. Regulatory Affairs 1001 U.S. Highway 202 Raritan, NJ 08869 (908_ 218-81788

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

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

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0038

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

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

NOV 26 2004

Telephone: (732)-235-4687

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

FACILITY LOCATIONS ( Sites ) - See 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 animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs			16		16
5. Cats					
6. Guinea Pigs			2		2
7. Hamsters					
8. Rabbits		11	108		119
9. Non-human Primates					
10. Sheep					
11. Pigs			57		57
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 rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

\_\_\_\_\_  
(Type or Print)

DATE SIGNED

11/22/04

CUSTOMER ID AND SITE ADDRESS:

ID: 184

1. UMDNJ-RWJMS  
Basic Science Building-Research tower  
675 Hoes Lane, RB01  
Piscataway, NJ 08854-5635

Phone: 732-235-4570

County: Middlesex

2. UMDNJ-RWJMS  
Medical Education Building  
One Robert Wood Johnson Place  
New Brunswick, NJ 08901-0019

Phone: 732-235-7913

County: Middlesex

3. UMDNJ-RWJMS  
Education and Research Building  
401 Haddon Avenue  
Camden, NJ 08103

Phone: 856-757-9650

County: Camden

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

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

Species: Swine  
Number: 59

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

Exception: An exception to the standard found in Section 3.128 was requested by the principal investigator for Protocol Number I02-075 and I03-029 based upon scientific necessity and was granted by the IACUC. The explanation is summarized as follows: During observation periods lasting 8 to 12 hours and during a drug infusion period of 48 hours, each pig needs to be confined in a metabolic cage that restricts its horizontal movements. The metabolic cage measures 1.5' wide, 3' long and is 4' high. The pig will be able to stand or recline but will have restricted movement so as not to pull out the pulmonary artery and aortic catheter which would result in exsanguination of the drug infusion catheter. The maximum period of time any individual pig would be confined to the metabolic cage would be 56 hours. The pigs will be transferred to a holding cage with approximately 18 square feet of floor space when they are not being experimentally observed and not being infused.

1/13/05  
\_\_\_\_\_  
Date

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )	1. CERTIFICATE NUMBER: 22-R-0076 CUSTOMER NUMBER: 189	FORM APPROVED OMB NO. 0579-0036
Camden County College P.O. Box 200 College Drive Blackwood, NJ 08012  Telephone: (856)-227-7200		
<b>SEP 27 2004</b>		

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 )

*Veterinary Technology Dept. (Tru 109)* 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 animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not 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 for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasr such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	8	0	8	0	8
7. Hamsters	0	0	0	0	0
8. Rabbits	12	0	12	0	12
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

**ASSURANCE STATEMENTS**

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

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

DATE SIGNED

*9/23/04*

NOV 24 2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

*Product Safety Labs  
725 Hamburg Rd  
East Brunswick, NJ  
09816  
(732)-438-5100*

Telephone: (732)-438-5100

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

FACILITY LOCATIONS (Sites) - See 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 animal 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 reason such drugs were not used must be attached to this report )	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs		7147		187	7334
7. Hamsters		89			89
8. Rabbits		2243	124	125	2537
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
<i>Ferrets</i>		269			269

**ASSURANCE STATEMENTS**

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

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

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED 11/22/04
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*(Signature)*

**ATTACHMENT TO USDA/APHIS ANNUAL REPORT OF RESEARCH FACILITY**

**EXPLANATION OF COLUMN "E" ENTRIES**

10/01/03 through 9/30/04

**125 Rabbits – Eye Irritation Test (OPPTS 870.2400):** Thirteen (19) 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 (106) 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.

**45 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  $\leq 1$  in<sup>2</sup>. 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.

**187 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  $\leq 1$  in<sup>2</sup>. 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  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )	1. CERTIFICATE NUMBER: 22-R-0099 CUSTOMER NUMBER: 194	FORM APPROVED OMB NO. 0579-0036
University Of Medicine & Dentistry Of Nj School Of Osteopathic Medicine 2 Medical Center Drive Stratford, NJ 08084  Telephone: (856) -566-6119		

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

FACILITY LOCATIONS ( Sites ) - See 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 animal 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 tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabblts	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	7	0	7
12. Other Farm Animals	0	0	0	0	0
	0	0	0	0	0
13. Other Animals	0	0	0	0	0
	0	0	0	0	0
	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 rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ( Chief Executive Officer or Legally Responsible Institutional Official )	DATE SIGNED 11/19/04
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UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

Telephone: (973) -844-7000

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

FACILITY LOCATIONS ( Sites ) - See 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 animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs			10		10
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Nonregulated Species					
mice					7625

**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 res teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inr 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 Legaly Responsible Institutional Official )

SIGNATURE

DATE SIGNED

11/30/04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0108  
CUSTOMER NUMBER: 193

FORM APPROVED  
OMB NO. 0579-0036

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

Exxonmobil Biomedical Sciences, Inc.  
P.O. Box 971  
1545 Route 22 East  
Annandale, NJ 08801

Telephone: (908) -730-1100

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs	0	102	0	0	102
7. Hamsters					
8. Rabbits	0	27	0	0	27
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 rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

L ( Type or Print )

DATE SIGNED

11/15/04

**Facility Locations for ExxonMobil Biomedical Sciences, Inc.**

The following is the only location where ExxonMobil Biomedical Sciences, Inc. housed or used animals in actual research, testing or experimentation, or held animals for these purposes.

ExxonMobil Biomedical Sciences, Inc.  
1545 Route 22 East  
Annandale, NJ 08801

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0116  
CUSTOMER NUMBER: 695

FORM APPROVED  
OMB NO. 0579-0036

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

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

Telephone: (609) -799-2295

NOV 29 2004

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	2	18	0	0	18
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

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

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

TIONAL OFFICIAL ( Type or Print )

DATE SIGNED

11/22/04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

Bartons West End Farms Inc  
161 Janes Chapel Road  
Oxford, NJ 07863

Telephone: (908) -637-4427

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	123	36	0	159
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	9	0	9
9. Non-human Primates	0	7	0	0	7
10. Sheep	0	0	0	0	0
11. Pigs	0	20	<del>47</del> 54	0	54
12. Other Farm Animals	-	-	-	-	-
Cows	0	0	4	0	4
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 res teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

( Type or Print )

DATE SIGNED

**FACILITY LOCATIONS (SITES):**

**ID: 701**

161 Janes Chapel Road  
Oxford, NJ 07863

And

PO Box 290  
Lakewood, PA 18439

DEC 06 2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0118  
CUSTOMER NUMBER: 1672

FORM APPROVED  
OMB NO. 0579-0036

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

Pediatric Cardiology  
137 Pavalion Avenue  
Long Branch, NJ 07740

Telephone: (908) -870-1611

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

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

*We are inactive will be starting in spring.*

**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 rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary int 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 )

SIC

DATE SIGNED

*11/30/04*

APF

( AUG 91 )

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )	1. CERTIFICATE NUMBER: 22-R-0123 CUSTOMER NUMBER: 1824	FORM APPROVED OMB NO. 0579-0036
County College Of Morris Veterinary Tech. Program 214 Center Grove Road Randolph, NJ 07869  Telephone: (973) -328-5340		

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

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

**ASSURANCE STATEMENTS**

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

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

DATE SIGNED  
 9/22/04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0124  
CUSTOMER NUMBER: 1828

FORM APPROVED  
OMB NO. 0579-0036

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

Aventis  
Route 202-206  
Box 6800 Jr2-203a  
Bridgewater, NJ 08807

NOV 24 2004

Telephone: (908)-231-3317

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	191	36	0	227
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	1211	5099	0	6310
7. Hamsters	0	0	0	0	0
8. Rabbits	0	132	11	2	145
9. Non-human Primates	0	12	48	0	60
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

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

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

S:

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

DATE SIGNED

22 Nov 04

AP

( Print S. S. S. S. S. S. )





November 22, 2004

**USDA Annual Report**  
**Registration #: 22-R-0124**

**Explanation of Category 'E' Animals**

**1. Number of Animals, Species and Procedure Used:**

2 rabbits - During repeat dose toxicity study with a 28-Day recovery period of an asthma drug, at high dose, animals experienced progressive clinical signs and were euthanized.

**2. Justification for procedure:**

The international regulatory process to approve new drug formulations and candidate drugs requires drug safety assessments. The goal of these studies is to investigate the toxicity of a new drug or formulation. The administration of any pain relieving drugs to these animals could interact and alter the results of the study.

**3. Procedure required by:**

Agency: FDA      Federal Food, Drug, and Cosmetic Act CFR: 505 (4) (i) (1) (A)

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0125  
CUSTOMER NUMBER: 11697

FORM APPROVED  
OMB NO. 0579-0036

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

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

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

FACILITY LOCATIONS ( Sites ) - See 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 animal 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 tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	/	9	/	9
5. Cats	0		0		0
6. Guinea Pigs	0		0		0
7. Hamsters	0		0		0
8. Rabbits	0		3		3
9. Non-human Primates	0		0		0
10. Sheep	0		0		0
11. Pigs	1		36		36
12. Other Farm Animals	0		0		0
13. Other Animals	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 rese teaching, testing, surgery, or experimentation were followed by this research facility.
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- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

DATE SIGNED

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

Telephone: (732)-918-0207

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

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

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

11-22-04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

NOV 26 2004

Telephone: (607) -674-9414

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	109	0	0	109
5. Cats	0	50	0	0	50
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual res teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

11/22/04

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )	1. CERTIFICATE NUMBER: 22-R-0132 CUSTOMER NUMBER: 188	FORM APPROVED OMB NO. 0579-0036
Gibraltar Laboratories Inc 122 Fairfield Road Fairfield, NJ 07004  Telephone: (973)-227-6882		

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY** ( Attach additional sheets if necessary or use APHIS Form 7025A )

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

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ( Chief Executive Officer or Legally Responsible Institutional Official )	E SIGNED 2/20/04
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( AUG 91 )

time period: 10/1/03 - 3/10/04 *TJ*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

William Paterson University Of New Jersey  
Department Of Biology  
300 Pompton Road  
Wayne, NJ 07470  
  
Telephone: (973) -720-3440

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

**SCIENCE HALL ROOMS 5206-208** FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

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

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rest teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGN

DATE SIGNED  
**10/24/07**

APHIS  
( AUG 91 )

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
22-R-0135

CUSTOMER NO.  
22320

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)

TRANSAVE INC  
11 DEER PARK DRIVE SUITE 117  
MONMOUTH JUNCTION, NJ 08852-1923

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)

TRANSAVE INC  
MONMOUTH JUNCTION, NJ 08852-1923

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		32	6		38
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of 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 AND TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

09/30/2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0136  
CUSTOMER NUMBER: 750

FORM APPROVED  
OMB NO. 0579-0036

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

Drug Research Laboratories Inc  
407 N Second Street  
Camden, NJ 08102

(begins March 04)  
thru 30 Sept. 04

Telephone: (856)-541-7115

**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)

Drug Research Labs in Petkasie, PA (2023 Ridge Road) 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 animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the proceduras, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	0	5	0	5
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
Ferrets	0	225	0	0	225

**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 res 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 ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in 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 )

DATE SIGNED  
10-30-04

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 34-R-0147  
CUSTOMER NO. 10106

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)

WEST MICHIGAN REGIONAL LABS  
3201 BURTON ST., SE  
GRAND RAPIDS, MI 49506

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)

WEST MICHIGAN REGIONAL LABS  
GRAND RAPIDS, MI 49506

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			4		4
5. Cats	3		34		34
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	5		78		78
9. Non-Human Primates					
10. Sheep					
11. Pigs			49		49
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

11/09/2004

OCT 1 2 2004

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

See attached form for additional information.

Interagency Report Control No. *JP*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 34-R-0149  
CUSTOMER NUMBER: 13477

FORM APPROVED  
OMB NO. 0579-0036

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

Grand Valley State University  
401 W Fulton  
Grand Rapids, MI 49504

Telephone: (616)-336-7265

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal 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 an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep	<i>This facility did not use any animals covered by AWA regulations</i>				
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 rest teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

DATE SIGNED

10/1/04

which is obsolete.)

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

<b>1. REGISTRATION NO.</b> 34-R-0151	<b>CUSTOMER NO.</b> 111	<b>FORM APPROVED</b> OMB NO. 0579-0036
<b>2. HEADQUARTERS RESEARCH FACILITY</b> (Name and Address, as registered with USDA, include Zip Code)		
HENRY FORD HOSPITAL 2799 W GRAND BLVD DETROIT, MI 48202-2689		

**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)**

HFHS DETROIT, MI 48202	HFHS DETROIT, MI 48201
HFHS DETROIT, MI 48201	

**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			144		144
5. Cats					
6. Guinea Pigs					
7. Hamsters			2		2
8. Rabbits			137		137
9. Non-Human Primates					
10. Sheep					
11. Pigs			6		6
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)

<b>SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL</b>	<b>NAME &amp; TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL</b> (Type or Print)	<b>DATE SIGNED</b> 11/03/2004
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See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 34-R-0152  
CUSTOMER NUMBER: 13343

FORM APPROVED  
OMB NO. 0579-0036

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

Midwest Animal Blood Services Inc  
Po Box 626 4933 Bird Dr.  
Stockbridge, MI 49285

Telephone: (517) -851-8244

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs		5	9		14
5. Cats			62		62
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Goat		5			5
13. Other Animals					
Nonregulated					
Ulama		1			1

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 rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
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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  
(ecutive Officer or Legally Responsible Institutional Official )

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

DATE SIGNED

11-29-

256

This report is required by law (? USC 21 43) 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

Set reverse side for additional information

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)	1 REGISTRATION NO. 22-V001 655	FORM APPROVED OMB NO. 0679-0036
2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code) Department of Veterans Affairs R&D Computing Center 103 Gay Street Baltimore, MD 21202-4051		
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)

Station: 561 VANJ Health Care System	
385 Tremont Ave. (15) East Orange, NJ 07018	

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 purpose	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 those 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	24	0	24
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
					24

**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 (Chief Executive Officer) I certify that the
SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

DATE SIGNED
10-13-04