

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0001  CUSTOMER NUMBER: 158	FORM APPROVED OMB NO. 0579-0036  <i>[Signature]</i>
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)		
Bell Labs Lucent Technologies 600 Mountain Avenue P. O. Box 636 Murray Hill, NJ 07974 <i>JAN 02 2002</i> Telephone: (908) -582-5696 <i>JAN 02 2003</i>		

**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 )**

## **ASSURANCE STATEMENTS**

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

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

SIGNATURE OF:

DATE SIGNED  
12/30/02

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FCRM APPROVED  
OMB NO. 0579-0036

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

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

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

FACILITY LOCATIONS(sites)

See Attached Listing

Laboratory Building - PH&EL

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

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

ASSURANCE STATEMENTS

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

10/28/02

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

See reverse side for additional information.

Interagency Report Control No  
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.  
22-R-0012 172

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)  
ETHICON, INC.  
P.O. BOX 151  
SOMERVILLE, NJ 08876-015

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

### FACILITY LOCATIONS(sites)

ETHICON RESEARCH FOUNDATION  
SOMERVILLE, NJ 08876

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

A.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	6		25		25
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	28		131		131
9. Non-Human Primates					
10. Sheep			6		6
11. Pigs			621		621
12. Other Farm Animals					
Goats			24		24
13. Other Animals					

### ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
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- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

10/30/2002

DEC 02 2002 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-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) -538-6601	

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 ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs			26		26
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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( Chief Executive Officer or Legally Responsible Institutional Official )

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

DATE SIGNED

11/29/02

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE1. CERTIFICATE NUMBER: 22-R-0016  
CUSTOMER NUMBER: 174FORM APPROVED  
OMB NO. 0579-0026ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )Johnson & Johnson Consumer Products, Inc.  
Johnson & Johnson Res. Found.  
Research & Development  
199 Grandview Road  
Skillman, NJ 08558  
Telephone: (908) -874-1350

NOV 20 2002

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 )

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	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
Dogs					:
Cats					:
Guinea Pigs		4			4
Hamsters					
Rabbits		30			30
Non-human Primate					
Sheep					
Pigs		20	20		40
Other Farm Animals					
Other Animals -					

## SURANCE STATEMENTS

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( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

19/NOV/02

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

NOV 26 2002

1. REGISTRATION NO. CUSTOMER NO.  
22-R-0020 175

FORM APPROVED  
OMB NO. 0578-0036

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

UNIVERSITY OF MEDICINE & DENTISTRY OF NEW JERSEY  
185 S. ORANGE AVENUE  
MSB A-604  
NEWARK, NJ 07101  
(973) 972-5455

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

FACILITY LOCATIONS(sites)

See Attached Listing	Research Animal Facility Medical Science Building (MSB)	A-Level UMDNJ/New Jersey Medical School
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REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

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			36		36
5. Cats			44		44
6. Guinea Pigs			13		13
7. Hamsters					
8. Rabbits	1	5	57		63
9. Non-Human Primates			8		8
10. Sheep					
11. Pigs			115		115
12. Other Farm Animals					
13. Other Animals					
Gerbils		16			16
Woodchucks		36			36

ASSURANCE STATEMENTS

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

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

DATE SIGNED

11/25/02

DEC 04 2002

See attached form for additional information

Interagency Report Control No.: *open*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

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 animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats			13		13
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			24		24
9. Non-human Primate	7	10	9		19
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Marmosets		24			24
Peromyscus Mice		894			894

ASSURANCE STATEMENTS

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IN BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
Title Officer or Legally Responsible Institutional Official

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	DATE SIGNED
Bolete.	12-6-2002

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  
P.O. Box 1059  
Piscataway, NJ 08854

NOV 29 2002

Telephone: (908) -932-2880

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	8	24			24
5. Cats	2	3	8		11
6. Guinea Pigs		10	275		285
7. Hamsters					
8. Rabbits	5	1	50		51
9. Non-human Primate		2	3		5
10. Sheep	10	8			8
11. Pigs	40	12			12
12. Other Farm Animals					
Deer	25	4			4
13. Other Animals					
Gerbils	16	150			150
Spiny Mice		31			31
Hedgehog		1			1

ASSURANCE STATEMENTS

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

TE SIGNED  
*26-02*

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Rutgers, The State University of New Jersey

The following sites have been combined into one site:

Busch Campus  
Nelson Biological Laboratories, D108  
604 Allison Road  
Piscataway, NJ 08854

Cook Campus  
NJ Agricultural Experimental Station  
PSARF Complex & Bartlett Hall  
New Brunswick, NJ 08901

Newark Campus  
Smith & Aidekman Halls  
197 University Avenue  
Newark, NJ 07102

The following site has been deleted:

Camden Campus  
Biology Department  
Building 7002 Science  
Camden, NJ 08101

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)		Bristol-Myers Squibb Company P.O. Box 4000 Princeton, NJ 08543  Telephone: (609) -252-4000	DEC 04 2002
Lawrenceville, NJ		Attachment A #1	

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 ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E )
4. Dogs	13	0	59	0	72
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	23	276	0	299
7. Hamsters	14	4	3	0	21
8. Rabbits	0	0	13	0	13
9. Non-human Primate	24	1	70	0	95
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

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

SIGNATURE OF C.E.O.

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL / TYPE OR PRINT

DATE SIGNED

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)

Somerville, NJ

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

Telephone: (609) -252-4000

DEC 04 2002

Attachment A #3

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 (Situs) - See Attached Listing

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

Animals Covered By The Animal Welfare Regulations	A. Number of animals being cured, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	B. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	C. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to 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 Primate	150					
10. Sheep						
11. Pigs						
12. Other Farm Animals						
13. Other Animals						

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all 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.
- 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

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

SIGNATURE

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

which is obsolete.

DATE SIGNED

1/25/02

NOV. 6, 2002 11:05AM

609 818 3675

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

NO. 371 E. 2

Interagency Report Control No.:

See attached form for  
additional informationUNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICEFORM APPROVED  
OMB NO. 0579-C036ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Hopewell (Pennington) NJ

1. CERTIFICATE NUMBER: 22-R-0028  
CUSTOMER NUMBER: 168Bristol-Myers Squibb Company  
P.O. Box 4000  
Princeton, NJ 08543  
Telephone: (609) -252-4000

DEC 04 2002

Attachment A #4

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 (Site) • See Attached Listing

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY / Attach additional sheets if necessary or use APHIS Form 7023A1

A.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4 Dogs			31		31
5. Cats	N/A				0
6. Guinea Pigs		1551	33		1584
7. Hamsters			204		204
8. Rabbits		22	325		347
9. Non-human Primate			23		23
10. Sheep	N/A				0
11. Pigs	N/A				0
12. Other Farm Animals					
	N/A				0
13. Other Animals					
Xenopus		16			16

## ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all 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.
- 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

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

SIGNATURE OF C.E.O.

IN NAME &amp; TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL / TYPE OR SIGN

DATE SIGNED

11/25/2

A #4-11/11/02

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.  
22-R-0031 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.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs			54		54
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs			14		14
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of 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
		11/26/2002

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0034  CUSTOMER NUMBER: 727	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )		
Nextran Company 303-B College Road East Princeton, NJ 08540 Telephone: (609) -243-0009		
<i>OCT 21 2002</i>		

**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 )**

## **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

<b>CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL</b> <b>( Chief Executive Officer or Legally Responsible Institutional Official )</b>		
SIGNAT	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED 10/13/03

APHIS Form 7023 Site List

The following sites have been reported by the facility.

---

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

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NEXTRAN COMPANY  
901 CARPENTER RD.  
ALBANY, OH 45710

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

DEC 09 2002

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

See attached form for additional information

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE		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 Telephone: (609) -896-5010	

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

FACILITY LOCATIONS Science & Technology Center - Room S-151

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

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
spiny mice		240			240

ASSURANCE STATEMENTS

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

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

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

DATE SIGNED

11-27-02

DEC 02 2002 See attached form for additional information

Interagency Report Control (RM)

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

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

Telephone: (609) -514-2437

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 )

Bracco Research USA

FACILITY LOCATIONS ( Sites ) - See Attached Listing

SAME AS ABOVE ADDRESS

305 College Rd East, Princeton, NJ 08540

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

A.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	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 Primate	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

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

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

SIC

APT

( AUG 91 )

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

s obsolete.

DATE SIGNED

11/26/02

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 <span style="font-size: 2em;">OK</span>
OCT 25 2002		
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )		
Ortho-Clinical Diagnostics, Inc. Regulatory & Clinical Affairs 1001 U.S. Highway 202 Raritan, NJ 08869		
Telephone: (908) -218-8177		

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

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

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

## **ASSURANCE STATEMENTS**

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

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

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

| DATE SIGNED

22-R-0064

## **APHIS Form 7023 Site List**

The following sites have been reported by the facility:

---

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

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

Sterlingbrook Equine Trauma Center  
City Route 513 Box 344  
Pittstown, NJ 08867

Robert Wood Johnson-Pharmaceutical Research Institute  
Farming Complex (RWJ-PRI)  
County Highway 513  
Pittstown, NJ 08867

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

See reverse side for additional information.

Interagency Report Control No  
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

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

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

WILLIAM PATERSON UNIVERSITY OF NEW JERSEY  
300 POMPTON ROAD  
WAYNE, NJ 07470  
(973) 720-2480

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

FACILITY LOCATIONS(sites)

See Attached Listing

SCIENCE HILL ROOMS 206-208

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

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

**ASSURANCE STATEMENTS**

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

10/3/02

HEADQUARTERS

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(AUG 91)

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0066 CUSTOMER NUMBER: 184	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )		University Of Medicine & Dentistry Of Nj Robert W. Johnson Med. School 675 Hoes Lane Piscataway, NJ 08854  Telephone: (732) <del>235-4587</del> 235-4570

**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 )**

## **ASSURANCE STATEMENTS**

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

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

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

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

**DATE SIGNED**

10|29|02

All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

### APHIS Form 7023 Site List

The following sites have been reported by the facility.

---

Registration Number: 22-R-0066

Customer Number: 184

Facility: University of Medicine & Dentistry of New Jersey  
675 Hoes Lane  
Piscataway, NJ 08854  
(732) 235-4570

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Vivarium  
Education and Research Building  
401 Haddon Avenue  
Camden, NJ 08103

UMDNJ-Robert Wood Johnson Medical School  
Medical Education Building  
One Robert Wood Johnson Place  
New Brunswick, NJ 08901

UMDNJ-Robert Wood Johnson Medical School  
Basic Science Building, RB01  
675 Hoes Lane  
Piscataway, NJ 08854

Barton's West End Facilities

161 Jane's Chapel Road  
Oxford, NJ 07863

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

See reverse side for additional information.

Interagency Report Control No  
0186-GCA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.  
22-R-0075 188

FORM APPROVED  
OMB NO. 0575-0135

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

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,  
include Zip Code)  
GIBRALTAR LABORATORIES, INC.  
122 FAIRFIELD ROAD  
FAIRFIELD, NJ 07004  
(973) 227-8882

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(ses)

See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which 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)	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	38	0	0	38
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

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

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

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

SIGN

DATE SIGNED

1/15/03

APHIS  
(AUG 91)

1 - HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE		1. CERTIFICATE NUMBER: 22-R-0076 CUSTOMER NUMBER: 189	FORM APPROVED OMB NO. 0579-0036
OCT 07 2002 ANNUAL REPORT OF RESEARCH FACILITY ( TYPE OR PRINT )		Camden County College P.O. Box 200 College Drive Blackwood, NJ 08012  Telephone: (609) -227-7200	

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

9/09/02

NOV 18 2002

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-0086 CUSTOMER NUMBER: 191	FORM APPROVED OMB NO. 0579-0036 <i>CJN</i>
ANNUAL REPORT OF RESEARCH FACILITY ( TYPE OR PRINT )		Nabisco, Inc. 161 Sanitarium Road Sherburne, NY 13460 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.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	1	8116	116 0	0	116
5. Cats	0	850	0	0	50
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
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 such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

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

NAL OFFICIAL

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

DATE SIGNED

*9/19/02*

DEC 09 2002

See attached form for additional information

Interagency Report Control No. *[Signature]*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0099  
CUSTOMER NUMBER: 194

FORM APPROVED  
OMB NO. 0579-0036

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

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

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

SIR

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

DATE SIGNED

11/26/02

NOV 29 2002

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-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 animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters			0		0
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice		193	6865		7058
Rats			22		22

ASSURANCE STATEMENTS

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/25/02

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

See reverse side for additional information

Interagency Report Control No  
0180-DOA-LAN

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0110 CUSTOMER NO. 6209

FORM APPROVED  
OMB NO 0579-0039

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

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,  
include Zip Code)  
MORRISTOWN MEMORIAL HOSPITAL  
100 MADISON AVENUE  
MORRISTOWN, NJ 07962  
(973) 871-8256

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

### FACILITY LOCATIONS(sites)

See Attached Listing

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

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

**INACTIVE**

### ASSURANCE STATEMENTS

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

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

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

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

DATE SIGNED

1/21/03

FAK 1 - HEADQUARTERS

RECORDED

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

OCT 28 2002

See reverse side for additional information.

Interagency Report Control No  
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

20-R-0116 695

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)

XBL (XenoBiotic Laboratories Inc)  
107 Morgan Lane  
Plainsboro, NJ 08536

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)

Same as above

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	0	11	0	0	11
5. Cats	1	0	1	1	0
6. Guinea Pigs					1
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 such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
4. The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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

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

S

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

DATE SIGNED

10/23/02

NOV 27 2002 See attached form for  
additional information

Interagency Report Control No.: *CPV*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

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

Telephone: (908) -637-4427

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	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	N/A	255	N/A	N/A	255
5. Cats	N/A	N/A	N/A	N/A	N/A
6. Guinea Pigs	N/A	N/A	N/A	N/A	N/A
7. Hamsters	N/A	N/A	N/A	N/A	N/A
8. Rabbits	N/A	N/A	N/A	N/A	N/A
9. Non-human Primate	N/A	N/A	N/A	N/A	N/A
10. Sheep	N/A	N/A	N/A	N/A	N/A
11. Pigs	N/A	N/A	N/A	N/A	N/A
12. Other Farm Animals	N/A	N/A	N/A	N/A	N/A
13. Other Animals	N/A	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 research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

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

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

), which is obsolete.

DATE SIGNED

*26 Nov 02*

22R117

## FACILITY LOCATIONS (Sites)

Barton's West End Farms, Inc.  
161 Jane's Chapel Road  
Oxford, NJ 07863

Alder Ridge Farms, Inc.  
PO Box 290  
Lakewood, PA 18439-0290

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

ASSURANCE STATEMENTS

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

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

SIGNATURE C

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

DATE SIGNED

(2) copies mailed Sept 27<sup>th</sup>, 2022

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

OCT 28 2002

Interagency Report Control No.: 100-00000

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0122 CUSTOMER NUMBER: 1804	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )		
Epigenesis Pharmaceutical, Inc. 7 Clarke Drive Cranbury, NJ 08512  Telephone: (609) -409-6080		

**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 )**

## **ASSURANCE STATEMENTS**

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

**NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL / Type or Print**

| DATE SIGNED

9/26/02

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0123 CUSTOMER NUMBER: 1824	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)		
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 animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	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 Primate	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**

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

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

SIGNATURE OF C.I.

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

DATE SIGNED  
9/26/02

<p>UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE</p> <p><b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )</p>	<p>1. CERTIFICATE NUMBER: 22-R-0125 CUSTOMER NUMBER: 11697</p>	<p>FORM APPROVED OMB NO. 0579-0036</p>
<p>Hackensack University Medical Center Institute For Biomedical Research David Joseph Jurist Research Bldg 30 Prospect Ave Hackensack, NJ 07601</p> <p>Telephone: (201) -996-2879</p>		

**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 )**

## **ASSURANCE STATEMENTS**

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the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

Quarters Research Facility Official  
Legally Responsible Institutional Official )

**NAME**

| DATE SIGNED

## HACKENSACK UNIVERSITY MEDICAL CENTER

30 PROSPECT AVENUE  
HACKENSACK, NJ 07601

OCT 25 2002

See attached form for additional information

OCT 25 2002

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

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

Telephone: (908) -918-0207

732

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	25 09	0	9
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 Primate	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

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

DATE SIGNED  
10-24-02

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. CUSTOMER NO.  
22-R-0131 16333

FORM APPROVED  
OMB NO 0579-C036

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

NOV 15 2002

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)

161 Sanitarium Rd

Sherburne, NY 13460

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

A.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	1	116	0		116
5. Cats	0	50	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

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

11/12/02

See subsection 10(7)(c)  
of the Act.

<p>UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE</p> <p>JAN 1 2003</p> <p><b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)</p>	<p>1. CERTIFICATE NUMBER: 22-R-0132 CUSTOMER NUMBER: 188</p>	<p>FORM APPROVED OMB NO. 0579-0036</p>
<p>Gibraltar Laboratories, Inc. 122 Fairfield Road Fairfield, NJ 07004</p> <p>Telephone: (973) -227-6882</p>		

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 Listings**

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

A.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	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 anaesthetic, 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 form)	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 anaesthetic, 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 form)	F. TOTAL NUMBER OF ANIMALS (C + D + E)
4. Dogs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Cats	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Guinea Pigs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Hamsters	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Rabbits	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
9. Non-human Primate	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Sheep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Pigs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Other Farm Animals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Other Animals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## **ASSURANCE STATEMENTS**

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

SIGNA

| DATE SIGNED

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( AUG 31 )

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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

FORM APPROVED  
OMB NO. 0579-0036

NOV 1 2002

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Public Health Research Institute  
225 Warren Street  
Newark, NJ 07103

Telephone: (973) 854-3100

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

FACILITY LOCATIONS (Sites) - See 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 ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E )
4. Dogs	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 Primate	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 research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

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

DATE SIGNED

*11-8-02*

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0006 CUSTOMER NUMBER: 169	FORM APPROVED OMB NO. 0579-0036  <i>CH</i>
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)		
Ortho Pharmaceutical Corporation Johnson & Johnson Pharmaceutical Rsrch & Dev Llc P O Box 300 Route 202 South Raritan, NJ 08869  Telephone: (908) -704-4310		
<i>NOV 26 2002</i>		

**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 |

#### **ASSURANCE STATEMENTS**

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

**NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL / Type or Print**

**DATE SIGNED**

## ATTACHMENT 1

USDA ANNUAL REPORT (2001-2002)Registration #: 22-R-0006

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

SPECIES	CATEGORY B	CATEGORY C	CATEGORY D	CATEGORY E
DOGS	0	202	145	0
GUINEA PIGS	0	0	160	0
RABBITS	0	42	0	0
NON-HUMAN PRIMATES	15	15	39	13

## ATTACHMENT 2

USDA ANNUAL REPORT (2001-2002)

Registration #: 22-R-0006

Animals Listed in Category E

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

SPECIES	NUMBER	PROCEDURE/JUSTIFICATION
Guinea Pigs	105	(b)(4)
Rabbits	16	
Dogs	52	

Non-Human Primates(Squirrel)	13	(b)(4)
---------------------------------	----	--------

- 1 Administration of anesthetics, analgesics or tranquilizing drugs must be withheld so as not to invalidate the evaluation of test compounds.
- 2 Preclinical toxicology and drug metabolism/pharmacokinetic studies are required in nonhuman species by the Food and Drug Administration, Good Laboratory Practice Regulations – CFR 21, Part 58 (Code of Conduct).
- 3 Spied, L.H., Lunley, C.E. and S.R. Walker. "Harmonization of Guidelines for Toxicity Testing of Pharmaceuticals by 1992." *Regulatory Toxicology and Pharmacology*. Vol 12, pp 179-211 (1990).

 See attached form for additional information

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0009 CUSTOMER NUMBER: 519	FORM APPROVED OMB NO. 0579-0036 
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> <b>( TYPE OR PRINT )</b>		Novartis Pharmaceuticals Corporation Novartis Pharmaceuticals Corporation Bldg 404, Rm 466 One Health Plaza East Hanover, NJ 07936  Telephone: (973) -781-8358

**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

## **ASSURANCE STATEMENTS**

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

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

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**USDA ANNUAL REPORT OF RESEARCH FACILITY FOR 2001-2002**  
**NOVARTIS PHARMACEUTICALS CORPORATION**  
**USDA Registration No. 22-R-0009**

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

	<u>Protocol Title</u>	<u>Species</u>	<u>Number</u>	<u>Days Without Exercise</u>	<u>Reason</u>
1.	(b)(4)	Dogs	2	36	Quantitative collection of excreta, containment of radioactivity
2.		Dogs	1	31	Quantitative collection of excreta, containment of radioactivity
3.		Dogs	3	11	Quantitative collection of excreta, containment of radioactivity
4.		Dogs	4	7	Quantitative collection of excreta, containment of radioactivity
5.		Dogs	1	8	Quantitative collection of excreta, containment of radioactivity
6.		Dogs	4	11	Surgical recovery of dogs implanted with telemetry devices

<u>Protocol Title</u>	<u>Species</u>	<u>Number</u>	<u>Days Without Exercise</u>	<u>Reason</u>
7. (b)(4)	Dogs	4	10	Surgical recovery of dogs implanted with telemetry devices
8.	Dogs	4	9	Surgical recovery of dogs implanted with telemetry devices
9.	Dogs	2	8	Surgical recovery of dogs implanted with telemetry devices
10.	Dogs	3	6	Cage rest post CSF collection

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

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

These primates were dosed with a pharmaceutical compound.

One animal experienced a fractured limb and was euthanized.

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

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

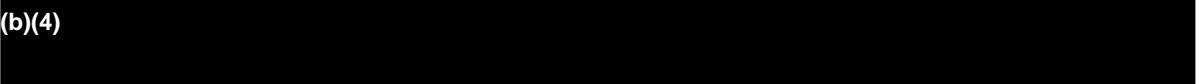
6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)



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

These dogs were dosed with a pharmaceutical compound.

Two dogs were found dead with no prior clinical signs.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 1.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
5. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

On day 70 this dog was suspected to have aspirated compound after dosing and was euthanized.

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

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

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

[REDACTED]

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 30. Number of animals classified as category "E" - 18.

3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.

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

These dogs were dosed with a pharmaceutical compound.

Fifteen dogs experienced compound related effects and were euthanized unscheduled. Three dogs experienced compound related effects, recovered and went on to complete the study.

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

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

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 14. Number of animals classified as category "E" - 4.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Two dogs were found dead, one on day 3 and one on day 8. Two dogs experienced compound related effects and were euthanized.

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

As soon as there were signs indicating that these animals were experiencing pain and distress, they were euthanized.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)



1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 1.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

One dog displayed compound related effects on study day 21 and was euthanized.

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

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

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

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

3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.

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

These dogs were dosed with a pharmaceutical compound.

Four dogs experienced compound related effects and were euthanized.

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

As soon as there were signs indicating that these animals were experiencing pain or distress, they were euthanized.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 40. Number of animals classified as category “E” - 4.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Three dogs were found dead on study day 41, 57 and 132 respectively. One dog experienced compound related effects and recovered.

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

(b)(4)

and subsequently recovered showing no adverse signs the following day and was able to complete the study.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)



1. Registration Number: 22-R-0009
2. Number of animals used in this study – 10. Number of animals classified as category "E" - 6.
3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Three dogs displayed compound related effects and were euthanized unscheduled. One dog was found dead on day 8 of the study. Two dogs experienced compound related effects at points during the study, recovered and were able to complete the study.

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

As soon as there were signs indicating that these animals were experiencing pain or distress, they were evaluated, monitored, and a decision made to euthanize if the animal did not improve.

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

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

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

**OPTIONAL COLUMN E EXPLANATION FORM**

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study - 40. Number of animals classified as category "E" - 1.

3. Species (common name) \_\_\_\_\_ Dogs \_\_\_\_\_ of animals used in this study.

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

These dogs were dosed with a pharmaceutical compound.

One animal experienced compound related effects in this study.

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

The above mentioned animal experienced (b)(4) activity on days 103 and 104 and fully recovered.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

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

3. Species (common name) \_\_ Crab-eating Macaque \_\_ of animals used in this study.

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

These animals were dosed with a pharmaceutical compound.

One monkey experienced an accidental death due to an enrichment device.

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

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)



1. Registration Number: 22-R-0009

2. Number of animals used in this study – 10. Number of animals classified as category "E" - 6.

3. Species (common name) Crab-eating Macaque of animals used in this study.

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

These animals were dosed with a pharmaceutical compound.

Six animals displayed compound related effects, recovered and went on to complete the study.

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

As soon as there were signs indicating that these animals were experiencing pain or distress, compound dosing was stopped. Their condition then improved.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

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

3. Species (common name) \_\_Crab-eating Macaque\_\_ of animals used in this study.

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

These animals were dosed with a pharmaceutical compound.

One animal experienced compound related effects.

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

This animal was treated for compound related effects and fully recovered.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study -60. Number of animals classified as category "E" - 1.

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

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

These animals were dosed with a pharmaceutical compound.

One rabbit was found dead with no prior severe clinical signs.

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

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study -30. Number of animals classified as category "E" - 9.

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

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

These animals were dosed with a pharmaceutical compound.

Seven rabbits were found dead, four rabbits on day 1 and three rabbits on day 2 of the study. One rabbit was euthanized after displaying compound related effects. One rabbit was euthanized as a result of a foot injury unrelated to the compound being dosed

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

Following dosing, the animals that were later found dead fell into a state of unconsciousness without signs of pain or distress. Observation for recovery from this state of unconsciousness could possibly have been masked by the use of analgesics and thus they could not be used.

As soon as there were signs indicating that the other two animals were experiencing pain or distress, they were euthanized.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

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

3. Species (common name) \_\_\_\_\_ Rabbits \_\_\_\_\_ of animals used in this study.

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

These animals were dosed with a pharmaceutical compound.

One rabbit exhibited (b)(4) and was euthanized.

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

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

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

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

3. Species (common name)\_\_\_\_Rabbits\_\_\_\_ of animals used in this study.

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

These animals were dosed with a pharmaceutical compound.

Six rabbits were euthanized after displaying compound related effects. The second phase of this study was subsequently cancelled.

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

As soon as there were signs indicating that these animals were experiencing pain or distress, they were euthanized.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 30. Number of animals classified as category "E" - 5.
3. Species (common name) Rabbits of animals used in this study.
5. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Three rabbits were found dead with no prior clinical signs and two rabbits were euthanized after displaying compound related effects.

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

As soon as there were signs indicating that these animals were experiencing pain or distress, they were euthanized.

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study - 30. Number of animals classified as category "E" - 3.

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

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

These animals were dosed with a pharmaceutical compound.

Two rabbits were found dead with no prior clinical signs and one rabbit was euthanized after displaying compound related effects.

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

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

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

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

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

## OPTIONAL COLUMN E EXPLANATION FORM

(b)(4)

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 30. Number of animals classified as category "E" - 9.

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

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

These animals were dosed with a pharmaceutical compound.

Six rabbits were found dead with no prior clinical signs and three rabbits were euthanized after displaying compound related effects.

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

As soon as there were signs indicating that these animals were experiencing pain or distress, they were euthanized.

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

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

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

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0028 CUSTOMER NUMBER: 168	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> (TYPE OR PRINT)		
New Brunswick, NJ		
Bristol-Myers Squibb Company P.O. Box 4000 Princeton, NJ 08543 Telephone: (609) -252-4000 Attachment A #2		
<i>DEC 04 2002</i>		

**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 ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	95	267	12	0	279
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	70	0	70
7. Hamsters	0	0	0	0	0
8. Rabbits	33	426	49	11	486
9. Non-human Primate	60	23	0	1	24
10. Sheep	0	0	6	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 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

**FICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
of Executive Officer or Legally Responsible Institutional Official )**

---

**SIGNATURE OF G.F.**

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

| DATE SIGNED

11/25/2

DEC 04 2002

Special Use:

### 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-0028**
2. Number : **190** of animals used in studies.
3. Species (common name): **Rabbits** of animals used in studies
4. Explain the procedure producing pain and /or distress.

The **Eleven Rabbits** included in column "E" was used in routine toxicity studies of new pharmaceutical compounds. New pharmaceutical compounds administered by the **oral** route(s) elicited a range of side effects some adverse, which are 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.

A#2-24

Special Use:

DEC 04 2002

#### 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-0028**

2. Number: **3** of animals used in studies.

3. Species (common name): **Cynomolgus Macaque** of animals used in studies

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

The **one cyno** included in column "E" was used in routine toxicity studies of new pharmaceutical compounds. New pharmaceutical compounds administered by the **oral** route(s) elicited a range of side effects some adverse, which are 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.

A#2 - 3/4

The following IACUC – approved exceptions to the dog exercise plan and Non-human primate plan for environmental enhancement also occurred between October 1, 2001, and September 30, 2002. Our dogs are given the opportunity for routine self-exercise in spacious indoor-outdoor runs. During the USDA accounting for research use, October 1, 2001, to September 30, 2002 approximately 202 of the dogs listed in column C and D 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 24-hour 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.

Also during research use between October 1, 2001, and September 30, 2002, three Non-human primates listed in column B and C of our 7023 form were allowed by the BMS New Brunswick IACUC to be housed for a period of time singularly for their own safety and well being. They were deemed by our Clinical Veterinarian to not be compatible when housed in groups of 2 or 3 as were the other Non-Human primates listed in categories B and C for this reporting period. During the time these monkeys remained housed singularly they received an additional enrichment program as recommended by our clinical Veterinarian

Sincerely,

(b)(6), (b)(7)c  


Dr. D. M. Stark D24-01  
609-252-4820

A#3-44

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Wallingford, CT

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

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

Telephone: (609) -252-4000

DEC 04 2002

Attachment 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)

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 ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E )
4. Dogs	8	19	17		36
5. Cats	0	0	0		0
6. Guinea Pigs	0	56	0		56
7. Hamsters	0	25	0		25
8. Rabbits	6	0	129		129
9. Non-human Primate	2	6	32		38
10. Sheep	0	0	0		0
11. Pigs	0	0	0		0
12. Other Farm Animals	0	0	0		0
			1		
13. Other Animals					
Gerbils	214	23	351	55	429

ASSURANCE STATEMENTS

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

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

SIGNATURE OF C.E.O.

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

DATE SIGNED

11/25/2

Re:

KCC

B-112

## Column E Explanation

DEC 04 2002

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-0028

2. Number 55 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.

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 10" high, 7" diameter glass beaker filled with 22-26° C water to a level of 6.5". For a period of 6 minutes the gerbil's swimming behaviors 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 the 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 \_\_\_\_\_

B-2/2

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

See attached form for  
additional information

**Interagency Report Control No.:**

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0028  CUSTOMER NUMBER: 168	FORM APPROVED OMB NO. 0579-0036
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )		
(East) Syracuse, NY		
Bristol-Myers Squibb Company P.O. Box 4000 Princeton, NJ 08543  Telephone: (609) -252-4000		
<i>DEC 04 2002</i>		
Attachment C		

**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 )**

## **ASSURANCE STATEMENTS**

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

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

SIGNATURE OF C.E.O. O

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

DATE SIGNED

11/25/2

Column E Explanation

DEC 04 2002

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-0028
2. Number of animals used in studies: 138
3. Species of animals used in studies: Dogs
4. Explain the procedure producing pain and/or distress.

Of the 138 dogs used in routine toxicity studies of new pharmaceutical compounds at this site, 38 were included in Column "E". New pharmaceutical compounds were administered to these animals by the oral and intravenous routes. Some compounds administered by each of these routes 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 and intravenous 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 Exceptions:

A total of 75 dogs on 7 separate toxicity studies were exempted from exercise during the course of this 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 these animals 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.



C- 2/3

DEC 04 2002

### 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-0028
2. Number of animals used in studies: 211
3. Species of animals used in studies: Nonhuman primates
4. Explain the procedure producing pain and/or distress.

Of the 211 nonhuman primates used in routine toxicity studies of new pharmaceutical compounds at this site, 18 were included in "Column E". New pharmaceutical compounds were administered to these animals by the intravenous and oral routes. Some compounds administered orally 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 Exceptions:

No exceptions to USDA standards and regulations applied to these animals 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.

C-3/3

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

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

DEC 04 2002

Telephone: (609) -252-4000

Attachment D

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	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	11	20	112	2	134
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	165	1	166
9. Non-human Primate	5	63	12	0	75
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 research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

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

SIGNATURE OF C.E.O. OR II

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

DATE SIGNED

1/25/2

Special Use:

DEC 04 2002

### 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-0028**
2. Number : **101** of animals used in studies.
3. Species (common name): **Dogs** of animals used in studies
4. Explain the procedure producing pain and /or distress.

The **2 dogs** included in column "E" were used in routine toxicity studies of pharmaceutical compounds. New pharmaceutical compounds administered by the **oral** route elicited a range of side effects some adverse, which are 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.

D-2/3

DEC 04 2002

Special Use:

### Column E Explanation

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1. Registration Number: 22-R-0028
2. Number : 60 of animals used in studies.
3. Species (common name): Rabbit of animals used in studies
4. Explain the procedure producing pain and /or distress.

The **rabbit** included in column "E" was used in routine toxicity studies of new pharmaceutical compounds. New pharmaceutical compounds administered by the **intramuscular** route elicited a range of side effects, some adverse, which were 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. **Intramuscular** 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.

D- 3/3

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1/01/02 - 09/30/02

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

Experimental Station - Site 006  
Wilmington, DE

1. REGISTRATION NO. 22-R-0028  
Customer number: 168

FORM APPROVED  
OMB NO. 0579-0036

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

Bristol-Myers Squibb Company  
PO Box 4000  
Princeton, NJ 08543

Attachment E

DEC 04 2002

Telephone Number: 609-252-4000

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

FACILITY LOCATIONS (Sites)


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	66	105	279	4	454
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	38	112	0	150
7. Hamsters	0	0	521		521
8. Rabbits	95	12	1490	2	1599
9. Non-human Primates	0	0	0	5	5
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

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all 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.
- 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.

L

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

DATE SIGNED

1/25/2

### **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 the 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**  
Customer ID: **168**  
Site Number: **006 Experimental Station**
2. Number of animals (total) used in this study: **12**  
Number of animals, in this study, classified as Category E: **4**
3. Species of animal used in this study: **Dog**
4. Explain the procedure producing pain and/or distress.

**Study Number:** T02-2-3

**Length of Study:** 10 days (toxicity study to evaluate the safety of a new drug candidate)

**Compound Class:** CNS

#### **Dog #3614841 (3001M) Signs Onset: Day 5**

On study day 5, this dog experienced seizures, was in lateral recumbency, and demonstrated increased respiratory effort. Temperature was 101.1F, heart rate 100 bpm, and respiratory rate 28 bpm. The animal was euthanized within one hour after seizures were observed. This study was a 10-day toxicity study. The appearance of seizures was interpreted to be drug related. Anesthetics, analgesics, tranquilizers were not used at the outset of the study due to the potential to interfere with interpretation of study results. A complete necropsy was conducted, and tissues collected for histopathology. Previous signs included loose stool on day 2 and a small amount of emesis on day 3.

#### **Dog #3600050 (3002M) Signs Onset: Day 6**

On study day 6, this animal was lethargic, not eating, and had demonstrated seizure activity and increased respiratory effort. Temperature was 101.2F, heart rate 80 bpm, and respiratory rate 36 bpm. The study was a 10-day toxicity study. The decision was made to euthanize the animal since the seizure activity was thought to be an effect of the compound. These events occurred on a weekend. Appropriate staff were contacted in order to make the decision to euthanize. The animal was euthanized six hours after the observation of seizure activity. Anesthetics, analgesics, tranquilizers were not used at the outset of the study due to the potential to interfere with interpretation of study results. A complete necropsy was conducted, and tissues collected for histopathology. Previous

*E-2/7*

clinical signs included loose stool on day 3 and a small amount of emesis on day 5.

**Dog #3608239 (3502F) Signs Onset: Day 6**

On study day 8, this animal demonstrated seizure activity and increased respiratory effort. Temperature was 100 F; heart rate 80 bpm; respiratory rate 40 bpm; mucous membranes light pink in color, and capillary refill time 2 seconds. The study was a 10-day toxicity study. The seizure activity was thought to be related to an effect of the drug. The animal was euthanized approximately 1.5 hours after the seizures were noted. Anesthetics, analgesics, tranquilizers were not used at the outset of the study due to the potential to interfere with interpretation of study results. A complete necropsy was conducted, and tissues collected for histopathology. Previous clinical signs included loose stool on day 3, small amount of emesis on day 4, and seizure activity and lateral recumbency following dosing on days 6 and 7, from which the animal recovered.

**Dog #3608379 (3501F) Signs Onset: Day 5**

On study day 7, this animal demonstrated seizure activity, loose black tarry stool, lateral recumbency, and emesis. The dog was euthanized within 1.5 hours of noting signs. This was a 10-day toxicity study. Seizure activity was thought to be drug related. Anesthetics, analgesics, tranquilizers were not used at the out set of the study due to the potential to interfere with interpretation of study results. A complete necropsy was conducted, and tissues collected for histopathology. Seizure activity was noted on days 5 and 6, but associated with time of dosing and clinical recovery.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods 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 anesthetics, analgesics or tranquilizers agents was not possible in any of these cases because of expected interference with the toxicity profile evaluation for this new pharmaceutical compound being tested. All 4 dogs were euthanized as soon as possible to relieve pain and distress.**

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: NA                    CFR: NA

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DEC 04 2002

**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 the 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**  
Customer ID: **168**  
Site Number: **006 Experimental Station**
2. Number of animals (total) used in this study: **50**  
Number of animals, in this study, classified as Category E: **2**
3. Species of animal used in this study: **Rabbit**
4. Explain the procedure producing pain and/or distress.

**Study Number:** **2002/07/10A**

**Length of Study:** **>30 days**

**Compound Class:** **Cardiovascular**

Rabbits were anesthetized 35/5 mg/kg i.m. ketamine/xylazine combination. Rabbits were shaved and prepared for aseptic (sterile) surgical procedure of the left femoral region. Anesthesia was maintained by 1-2% isoflurane/oxygen inhalant by mask.

An incision was made over the left femoral region. The left femoral artery was gently isolated from the surrounding tissues and ligated distally. Small forceps were placed under the artery to increase exposure. A second ligature was loosely placed proximally on the artery. A small incision (between the forceps jaws) was made in the artery to allow for insertion of a 3F Fogerty (balloon) catheter. The jaws of the forceps holding the artery up controlled any unwanted bleeding. The "balloon" catheter was inserted into the artery and advanced ~ 30cm into the aorta. The balloon was inflated (0.2 CC saline) and withdrawn to the aortic/femoral branch and deflated. This procedure was repeated three times and the balloon catheter was removed. The proximal ligature was tightened and the surgical site irrigated with sterile saline. A muscle and skin closure were performed with 4-0 PDS II "dissolving" sutures. Rabbits were recovered and given 5 mg/kg i.m. xylazine for post-op pain. Rabbits are maintained for 8-10 weeks on high cholesterol diet. After 8-10 weeks have passed, the terminal portion of the experiment is performed under anesthesia. After recovery, even weeks out, some foot and skin sores have appeared (left leg only). Loss of use of leg(s) have occurred due to clot formation in the lower aorta. Upon examination, rabbits do react as if these sores are painful (loss of appetite or reflex response). Antibiotic ointment are applied and IM antibiotics can be used where necessary. Mutilation of sore and toes could be from compromised blood supply, unwanted

E- 4/7

clot formation, or nerve damage. These signs are treated as soon as they are observed. Surgical repairs (under anesthesia) are performed when needed. If surgical repair is not possible, rabbits are sedated and euthanized by I.V. barbiturate overdose.

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

Although not apparent, some pain and or distress could be taking place for mutilations, loss of use of leg(s) and large sores to appear. However, only a small number of rabbits have appeared with these symptoms. When these symptoms appear, they are treated promptly. If a symptom becomes so severe (not responding to treatments) as to compromise normal physiologic function (as determined by DVM) and surgical repair is not possible, the rabbit is euthanized.

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

Agency: NA                    CFR: NA

E - 5/7

**Column E Explanation**

DEC 04 2002

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 the 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**  
Customer ID: **168**  
Site Number: **006 Experimental Station**
2. Number of animals (total) used in this study: **5**  
Number of animals, in this study, classified as Category E: **5**
3. Species of animal used in this study: **Squirrel Monkeys**
4. Explain the procedure producing pain and/or distress.

**Study Number:** **2001/10/11A**

**Length of Study:** **>30 days**

**Compound Class:** **CNS**

Five monkeys are trained on a conflict procedure, used as an animal model of anxiety. In the presence of one stimulus, animals press a lever to obtain food and in the presence of another stimulus, animals press a lever for food but also receive a negative stimulation. This causes a decrease in response rate, an effect reversed by anxiolytic drugs. The negative stimulation is delivered to the tail and is contingent upon animal's behavior. This electrical stimulation is of mild to moderate intensity (not to exceed 1.5 ma) and is brief (less than 500 msec). No more than 20 stimulation events in a session are delivered. Animals quickly learn not to press the lever in the presence of the stimulus signaling food and stimulation so after the initial training period, few stimulation s are administered in the absence of drugs.

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

The measure of anxiolytic effects in this procedure is the reversal of stimulation induced suppression of lever pressing. Therefore, during training, animals are subjected to stimulation in order to suppress their responding. This stimulation is "escapable" (if the animal does not press the lever, it will not receive stimulation). When this stimulation induced suppression of responding is reversed, the animals are subjected to more stimulation, but this reversal occurs only when auxiolytic drugs (tranquilizers) are administered. Since the main measure of the study

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depends on stimulation induced suppression of responding, pain relief would interfere with test results.

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: NA            CFR: NA

DEC 04 2002

APPENDIX B

Location of BMS - Research Facilities  
(Revised 9/26/02)

Licensee/Registrant Name: Bristol-Myers Squibb Company

Licensee/Registrant Number: 22-R-0028

**A. New Jersey** (All within 35 mile radius)

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

Building: G1 and G2  
Floor/Room: 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 B (continued)

### Location of BMS - Research Facilities (Revised 9/26/02)

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

(b)(6), (b)(7)c

#### *C. New York*

Name/Department: Bristol-Myers Squibb Company  
Address: POB 4755  
Building: 6000 Thompson Road  
Floor/Room: East Syracuse, NY 13221-4755  
Contact Person: 32,32A,6A  
N/A

(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

#### *E. Delaware*

Name/Department: Bristol-Myers Squibb Company  
Address: Rt. 141 & Henry Clay Road  
Building: E400  
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-0030 CUSTOMER NUMBER: 178	FORM APPROVED OMB NO. 0579-0036 <i>[Signature]</i>
ANNUAL REPORT OF RESEARCH FACILITY ( TYPE OR PRINT )		Merck & Company, Inc. 126 E Lincoln Avenue Po Box 2000 <del>KY 108-A8</del> RY 80M-160 Rahway, NJ 07065 Telephone: (732) <del>542-1000X</del> 594-6179 <i>NOV 26 2002</i>	

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 ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic. a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	38	519	1021		1540
5. Cats					
6. Guinea Pigs	52	2292	489	175	2956
7. Hamsters	151	2696	73		2769
8. Rabbits	37	2909	1598	1060	5567
9. Non-human Primate	3478	227	967		1194
10. Sheep					
11. Pigs					
12. Other Farm Animals					
horses	1		3		3
13. Other Animals					
ferrets		14	150		164
gerbils		60	12		72

ASSURANCE STATEMENTS

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

*11/22/02*

126 E Lincoln Avenue Rahway NJ 07065-4607 COUNTY: UNION	Telephone: (732) 594-6179
203 River Rd Somerville NJ 08876 COUNTY: SOMERSET	Telephone: (908) 685-3846
RD 1 Box 391 Oxford NJ 07863 COUNTY: WARREN	Telephone: (908) 637-4427
3535 General Atomics Ct San Diego CA 92121-1140 COUNTY: SAN DIEGO	Telephone: (858) 202-5466
WP44-201 West Point PA 19486-0004 COUNTY: MONTGOMERY	Telephone: (215) 652-6232
WP74-1 West Point PA 19486-0004 COUNTY: MONTGOMERY	Telephone: (215) 652-6093
PO Box 016960 (R289) Miami, FL 33136 COUNTY: DADE	Telephone: (305) 243-8912
20256 SW 360 <sup>th</sup> St Homestead FL 33034-4102 COUNTY: DADE	Telephone: (305) 245-1551
PO Box 549 Alice TX 78333 COUNTY: JIM WELLS	Telephone: (361) 664-4984
95 Castle Hall Road Yemassee SC 29945 COUNTY: BEAUFORT	Telephone: (843) 589-5190
466 Devon Park Drive Wayne PA 19087 COUNTY: CHESTER	Telephone: (215) 652-6232
New Iberia Research Center University of Louisiana 4401 W. Admiral Doyle Drive New Iberia LA 70560 COUNTY: IBERIA	Telephone: (337) 482-0250

**USDA Annual Report: October 1, 2001 – September 30, 2002**

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

**EXPLANATION OF ITEMS IN COLUMN E**

One hundred and seventy five guinea pigs were studied according to an IACUC-approved protocol to evaluate the efficacy of new antifungal compounds. The animals were exposed to virulent fungi and then treated with novel antifungal compounds. Only compounds that showed promising results in *in-vitro* tests were used. The minimum number of animals were used to provide reliable test results and the length of the study was limited to the time necessary to establish the model. The test animals were observed twice daily and moribund animals were euthanized. Commercially available anti-fungal 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.

In addition, 1060 rabbits were studied according to another IACUC-approved protocol. Inflammation was induced in one paw of each animal to test the analgesic properties of novel compounds. The minimum number of animals were used to provide reliable data and the length of the study was limited to 8 hours or less. Commercially available analgesics could not be administered because they would interfere with the interpretation of the data and defeat the purpose of the research. Professional veterinary medical care was provided throughout each study and any animals experiencing excessive or unexpected levels of pain and distress were removed from the study and euthanized.

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

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

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

NOV 20 2002

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 animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	56	175	11	29	215
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	276	0	0	276
7. Hamsters	0	0	0	0	0
8. Rabbits	37	106	0	0	106
9. Non-human Primate	12	26	25	0	51
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

SIGNATURE

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

DATE SIGNED

11/13/02  
Approved As To Form

LAW DEPT.

RCH

**Column E Explanation**

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

1. Registration Number: 22-R-0032

2. Number \_\_\_\_\_ of animals used in this study.

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

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

A total of 29 dogs were used to evaluate drug candidates for clinical trials were identified as Category E. Twenty-four dogs were given a cytotoxic chemotherapeutic drug for the treatment of cancer and 5 dogs were given a glucose lowering drug for treatment of diabetes. During the studies, these dogs presented with clinical signs of lethargy, weight loss, diarrhea, inappetance, dehydration and ataxia.

The studies were designed and conducted in accordance with the Food and Drug Administration guidelines. Veterinary personnel observed all animals daily and supportive care included fluids and nutritional supplements were provided.

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

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

Agency FDA      CFR 21 CFR 58.3(d)  
21 CFR 58.90

NOV 29 2002

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

See attached form for additional information

Interagency Report Control No.: *9702*

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

1. CERTIFICATE NUMBER: 22-R-0036  
CUSTOMER NUMBER: 181

FORM APPROVED  
OMB NO. 0579-0036

Schering Corporation  
Schering-Plough Research Inst.  
2015 Galloping Hill Road  
Kenilworth, NJ 07033  
  
Telephone: (908) -298-4000

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	366	159	0	525
5. Cats	0	0	25	0	25
6. Guinea Pigs	0	4,498	2,724	0	7,222
7. Hamsters	0	0	70	0	70
8. Rabbits	0	482	29	7	518
9. Non-human Primate	113	443	227	0	670
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
GERBILS	0	2,180	5,028	0	7,208
13. Other Animals					

ASSURANCE STATEMENTS

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL,

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

DATE SIGNED

*11/26/02*

APHIS Form 7023 Site List

The following sites have been reported by the facility.

---

Registration Number: 22-R-0036  
Customer Number: 181  
Facility: SCHERING CORPORATION  
2015 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033  
(908) 298-4000

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SCHERING-PLOUGH RESEARCH INST. Site 2  
P.O. BOX 32, ROUTE 94  
LAFAYETTE, NJ 07848

RESEARCH INSTITUTE Site 1  
2000 GALLOPING HILL RD  
KENILWORTH, NJ 07033

Registration Number: 22-R-0036

November 22, 2002

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

Dear Dr. Goldentyer:

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

**Summary of exceptions to the regulations and standards:**

The environmental enrichment program has exceptions for social housing for some nonhuman primates. Twenty-five rhesus monkeys are housed separately due to special study requirements for controlling and monitoring food consumption as part of a research project. Six cynomolgus monkeys were housed separately for brief periods (1-21days) while participating in drug metabolism or telemetric monitoring studies. Seven cebus monkeys were single housed during several studies to allow better individual observations and excluded from certain elevated enrichment devices. The justification was to increase their safety due to decreased motor skills possibly caused by test compounds. All the animals are included in all the other aspects of the environmental enrichment program. The protocols with the exemptions are approved by the IACUC and reviewed during the semi-annual program review.

One exception to the canine exercise program is to be reported. It involved the use of special canine metabolism cages for drug metabolism studies. The canine metabolism cages provide greater than 100%, but less than 200% of required space for exercise. The period of time in the cages was approximately 24 hours. Positive human interaction was greatly increased during this period. The protocols with the exemption were approved by the IACUC and reviewed during the semi-annual program review. The studies were infrequent and involved only five laboratory canines.

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

**Summary of exceptions to the regulations and standards:**

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

22 R36

1. Two hundred and five cynomolgus non-human primates were exempted from social housing for periods of time when required for collection of individual clinical signs and required randomization of the animals in studies or during the quarantine period. The exemption from social housing was variable depending on the duration of the individual study. All study protocols were reviewed and approved by the IACUC.
2. The Safety Evaluation Center has implemented new pair housing procedures for monkeys on most studies this year. Although, the new program greatly increases the number of pair housed non-human primates, the program has resulted in some temporarily single housed monkeys for reasons other than protocol, medical conditions and aggression. Reasons for temporary single housing include the lack of a suitable partner because of significant size differences, odd number of animals in the room and/or medical evaluation and treatment of only one of the partners. The number of primates temporarily single housed in this group was nine.

General Column "E" Justification Statement:

Listed below are the animals that retrospectively and prospectively may have experienced some pain or distress during the study for site 2.

All the studies were performed under GLP standards for future FDA submission. The studies were approved the IACUC and conducted in accordance with FDA requirements [21CFR 312.23(a)(8), 21 CFR 58, 62 FR 62922, and 59 FR 48746]. Seven rabbits listed in column "E" were used in these standard toxicological investigations for new drug development. The rabbits developed unexpected terminal medical complications while participating on study. The rabbits retrospectively have been added to the column "E". In regard to all studies, as a standard policy, the attending veterinarian is notified of any abnormal medical condition that may occur in any of the research animals. All animals are carefully monitored and if found to be in pain and/or distress during the course of the study are provided humane euthanasia.

NOV 27 2002 See attached form for  
additional information

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  <i>Ein</i>
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( 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 )

## **ASSURANCE STATEMENTS**

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

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

| DATE SIGNED

26 NOV 07

DEC 09 2002

Annual Report of Research Facility  
October 1, 2001 to September 30, 2002  
Huntingdon Life Sciences  
Registration Number 22-R-0040

**A) Explanation of Category E Studies**

**Note:** For all studies listed below, the Principal Investigator provided written justification to the Huntingdon Life Sciences Institutional Animal Care and Use Committee that agents may not be used to alleviate pain or distress due to the potential for interference with the compound under investigation. Use of these agents was withheld so as not to invalidate the evaluation of test compounds.

Species	Number of Category E Animals	Study Type/Regulatory Reference	Study Objective <sup>1</sup>	Study Guidelines <sup>2</sup>
Dogs	6	Animals were exposed to test compound via intravenous administration for a single dose. Test article effects were evident, resulting in discontinuation of dosing in 6 affected animals. This study was based on an FDA mandated study design.	A	
Rabbit	5	Animals were exposed to test compound via oral gavage, once daily for 2 weeks. The study was designed to determine preliminary toxicity assessment of the test article. Five rabbits died/euthanized due to test article effects. This study was based on an FDA mandated study design.	E	
Monkey	7	Animals were exposed to test compound via intravenous administration for 4 weeks. Dose was discontinued in seven animals exhibiting test article effects. This study was based on an FDA mandated study design.	AD	
Monkey	4	Animals were exposed to test compound via intravenous administration once weekly for eight weeks. Test article effects were evident in 4 animals. Affected animals were euthanized. This study was based on an FDA mandated study design.	AB	
Swine	11	Animals were to have been exposed to test compound via dermal administration once daily, for 13 weeks. Due to test article effects, dose administration was discontinued after 3 weeks. Eleven animals exhibiting test article effects were euthanized. This study was based on an FDA mandated study design.	C	

DEC 09 2002

**Annual Report of Research Facility  
October 1, 2001 to September 30, 2002  
Huntingdon Life Sciences  
Registration Number 22-R-0040**

Swine	5	Animals were exposed to test compound via oral gavage once daily for 28 days. Five animals were euthanized due to test article effects. This study was based on an FDA mandated study design.	AD
Swine	7	Animals were exposed to test compound via dermal administration once daily for 28 days. Test article effects were evident in 7 animals. This study was based on an FDA mandated study design.	C
Swine	13	Animals were exposed to test compound via dermal administration once daily for 28 days. Test article effects were evident in 13 animals. This study was based on an FDA mandated study design.	C

**B) Explanation of Category E Animals in which the use of agents to alleviate pain or distress was not withheld.**

Species	Number of Category E Animals	Study Type/Regulatory Reference	Study Objective <sup>1</sup>	Study Guidelines <sup>2</sup>
Rabbit	31	Animals were exposed to test compound via subcutaneous administration once daily for 2 weeks. Animals exhibiting test article effects received supplemental nutrition and were eventually euthanized.	E	a,b
Dog	3	Animals were exposed to test compound via 24 hour infusion. Three animals exhibiting test article effects were treated with anti-emetics, fluids, and nutritional supplementation. Dose was discontinued and affected animals were euthanized. This study was based on an FDA mandated study design.	A	
Dog	23	Animals were exposed to test compound once via subcutaneous administration. Twenty-three animals exhibited test article effects and were treated with analgesics and topical treatments. This study was based on an FDA mandated study design.	A	

DEC 09 2002

**Annual Report of Research Facility**  
**October 1, 2001 to September 30, 2002**  
**Huntingdon Life Sciences**  
**Registration Number 22-R-0040**

Dog	1	Animals were exposed to test compound via single intravenous administration. One animal died as a result of test article effects.	AD	c,d
Dog	1	Animals were exposed to test compound via intravenous administration, three times. One animal was euthanized due to test article effect. This study was based on an FDA mandated study design.	AF	
Dog	4	Animals were exposed to test compound via intravenous administration for 5 days. Test article effects were observed in 4 animals. Three were treated with analgesics, and one was euthanized. This study was based on an FDA mandated study design.	A	
Dog	1	Animals were exposed to test compound via oral gavage/ intravenous administration every 3 days. One animal was euthanized due to effects attributed to test article.	B	c,d,e
Monkey	2	Animals were exposed to test compound via oral administration once daily for 2 weeks. One animal was treated with supplemental nutrition, and one animal was euthanized due to effects attributed to test article. This study was based on an FDA mandated study design.	AD	
Monkey	2	Animals were exposed to test compound via intravenous infusion. Two animals were euthanized due to effects attributed to test article. This study was based on an FDA mandated study design.	A	
Monkey	3	Animals were exposed to test compound via intravenous administration for 5 days. Three animals exhibited test article effects. Dose was discontinued and animals were euthanized. This study was based on an FDA mandated study design.	A	
Cats	1	Animals were exposed to test compound via single intravenous administration. One animal was treated with analgesics for surgical complications. This study was based on an FDA mandated study design.	AF	

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Annual Report of Research Facility  
October 1, 2001 to September 30, 2002  
Huntingdon Life Sciences  
Registration Number 22-R-0040

- 1 A Assessment of systemic toxicity
- B Assessment of cardiovascular effects/toxicity
- C Assessment of dermal irritation
- D Assessment of pharmacokinetics/toxicokinetics
- E Assessment of maternal/embryo effects
- F Assessment of local toxicity (injection site)

<sup>2</sup> These studies were based on one of the following guidelines:

- a. ICH (International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use) Harmonized Tripartite Guidelines, Detection of Toxicity to Reproduction for Medicinal Products: Federal Register V59, No. 183, Sept.22, 1994- Study Design 4.1.3, Study for Effects on Embryo-Fetal Development.
- b. Japanese Ministry of Health & Welfare, PAB/PCD Notification No. 316, April 14, 1997.
- c. Guidelines for General Pharmacology Studies, Japanese Ministry of Health & Welfare, PAB/NDD, Notification No. 4, January 1991.
- d. CPMP-986-96 Points to Consider, Cardiovascular Assessments, December 1997.
- e. ICH (International Conference on Harmonization), Topic S7, Safety Pharmacology.

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

- 8 dogs were exempted from the exercise requirement for 5 days while on study, during data collection via subcutaneous telemetry implant.
- 4 dogs were exempted from the exercise requirement for 34 days during surgical recovery and test article delivery via continuous intravenous infusion.
- 10 dogs were exempted from the exercise requirement for 19 days due to surgical recovery and test article delivery via continuous intravenous infusion.
- 12 dogs were exempted from the exercise requirement for 27 days during surgical recovery and data collection via subcutaneous telemetry implant.
- 6 dogs were exempted from the exercise requirement for 6 days while on study, during data collection via subcutaneous telemetry implant.
- 10 dogs were exempted from the exercise requirement for 41 days during surgical recovery and data collection via subcutaneous telemetry implant.
- 6 dogs were exempted from the exercise requirement for 7 days while on study, in order to collect continuous metabolism samples.

OCT 28 2002

See attached form for  
additional information.

**Interagency Report Central No.:**

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0041 CUSTOMER NUMBER: 173	FORM APPROVED OMB NO. 0579-0036 <span style="font-size: 2em;">(V)</span>
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( 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 - animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs		920		170	1090
7. Hamsters					
8. Rabbits		283	14		297
9. Non-human Primate					
10. Sheep					
11. Pigs			501		501
12. Other Farm Animals					
13. Other Animals					
Cotton rats			57		57

## **ASSURANCE STATEMENTS**

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

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

SIGNA

DATE SIGNED

2000-00000

**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-0041

2. Number 170 of animals used in this study.

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

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

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

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

Pain medication could compromise the sensitization process.

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

Agency FDA 21 CFR 58  
ISO 10993:10

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

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-0050 CUSTOMER NUMBER: 520	FORM APPROVED OMB NO. 0579-0036 <i>CJM</i>
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )		
S G S, U.S. Testing Company, Inc. 291 Fairfield Avenue Fairfield, NJ 07004		
Telephone: (201) 575-5252 <i>973</i>		

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

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

Telephone: (201) -575-5252

973

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

**FACILITY LOCATIONS ( Sites ) - See Attached Listing**      **75 Passaic Avenue**  
**Fairfield, NJ 07004**

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

## **ASSURANCE STATEMENTS**

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

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

**DATE SIGNED**

Dec 2/02

SG 114102



Registration #22-R-0050

COMMENTS, APHIS FORM 7023

- A. The 172 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 29 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:

Dec 2 / 202  
Date

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	1. CERTIFICATE NUMBER: 22-R-0069 CUSTOMER NUMBER: 185	FORM APPROVED OMB NO. 0579-0036  C/HM
<b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )		
Consumer Product Testing Co., Inc. 70 New Dutch Lane Fairfield, NJ 07004  Telephone: X 973		
NOV 26 2002		

**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 |

## **ASSURANCE STATEMENTS**

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

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

DATE SIGNED

11/25/02

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Facility Registration Number: 22-R-0069

The animals listed in Column E of APHIS Form 7023 included 315 guinea pigs, 6 hamsters and 77 rabbits. The rabbits and hamsters were used on irritation studies. These studies are used to determine the dermal, ocular or oral mucosa irritation potential of the articles tested. The guinea pigs were used on sensitization studies. These studies were used to determine the sensitization potential of the products tested.

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

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

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

NOV 29 2002 See attached form for additional information

Interagency Report Control No: 11/27/02

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  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.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs		4600		248	4848
7. Hamsters		103			103
8. Rabbits		1696	2	155	1853
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets		187			187

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

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 / DATE OF SIGN.

DATE SIGNED

11/27/02

ELC  
12/2/02

Registration Number: 22-R-0082

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

**EXPLANATION OF COLUMN "E" ENTRIES**

10/01/01 through 9/30/02

**140 Rabbits – Eye Irritation Test (OPPTS 870.2400):** Three (3) of these animals vocalized following instillation of the test compound but immediately became calm after they were returned to their cage. Therefore, anesthetic was not considered. Although the remaining animals did not exhibit overt signs of pain or distress, they exhibited ocular irritation scores above an arbitrary threshold and were considered to be in distress as a result of their exposure to the test compound. Although in the eye irritation test ocular anesthetic may be used prior to instillation, repeated and/or prolonged anesthetic use could retard healing and possibly lead to collateral irritation and/or subsequent corneal infection. Therefore, ocular anesthetic was not used on the animals evidencing ocular irritation scores above this established threshold limit.

**15 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  $\leq 1 \text{ in}^2$ . Continuous or prolonged use of topical or systemic anesthetic agents during dermal irritation tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of irritation. If used, they might significantly alter the effects of the test compound and compromise study results.

**248 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  $\leq 1 \text{ in}^2$ . Continuous or prolonged use of topical or systemic anesthetic agents during dermal sensitization tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of sensitization. If used, they might significantly alter the effects of the test compound and compromise study results.

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0108 CUSTOMER NO. 193

FORM APPROVED  
OMB NO. 0579-0036

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

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

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

FACILITY LOCATIONS(sites)

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

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

A.	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		303		43	346
7. Hamsters					
8. Rabbits		74		10	84
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/25/2002

EE 12/2002

**APHIS Form 7023 Column E Explanation**

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

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1. Registration Number: 22-R-0108

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

Guinea Pigs (43) Rabbits (10)

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

Three study types were identified as potentially producing pain or distress in rabbits or guinea pigs at ExxonMobil Biomedical Sciences, Inc. (EMBSI) during the 2001 - 2002 APHIS census year. All three study types followed accepted regulatory or international test guidelines (OECD 404, 405 and 406) and were conducted for regulatory purposes. These study types and the related procedures are listed below:

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

The animals were not treated for pain or distress because the effects of the anesthetic/analgesic agents on the study outcome were not known. In ocular irritation studies, recovery is a key endpoint. Anesthetic/analgesic agents may affect this recovery process and may even increase the severity of the response. In guinea pig sensitization studies, the animals must be observed for a designated period of time and in some instances be rechallenged to generate meaningful data. Also, in the ocular irritation and dermal irritation studies where the animals received only a single exposure, any pain or distress that may have occurred did not persist or progress, i.e., the responses observed were transient.

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

Agency: Ocular Irritation Studies - OECD, Organization for CFR:  
Economic Cooperation and Development, Guidelines for  
the Testing of Chemicals, Test Guideline 405, 1987

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0127  
CUSTOMER NUMBER: 12287

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Ft Dodge Animal Health  
A Division Of Wyeth  
P O Box 5366  
Princeton, NJ 08543

OCT 3 2002

Telephone: (732) -631-5800

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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

A.	B.	C.	D.	E.	F.
Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					
5. Cats	0	24	0	0	24
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Gerbils	110	2310	0	173	2483

ASSURANCE STATEMENTS

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

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

10/25/02

*(Signature)*

11/12/02

USDA Annual Report - 2002  
Fort Dodge Animal Health  
Facility Registration Number: 22-R-0127

**Facility Locations:**

Quakerbridge and Clarksville Roads  
Princeton, New Jersey 08543  
(Note: This site closed June 30, 2002.)

USDA Annual Report -- 2002  
Fort Dodge Animal Health  
Facility Registration Number: 22-R-0127

The 173 gerbils reported in Category E were used in efficacy testing of proprietary, novel compounds for *in vivo* anthelmintic activity. The test compounds were administered as a single oral dose.

The gerbils were found dead during routine daily morbidity and mortality checks. Premonitory signs were not observed the day before. Therefore this finding was not anticipated. Because the interval between onset of signs, if any, and death could not be determined, an assumption has been made that these gerbils could have experienced more than transient pain or distress prior to death.

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