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 attached form for additional information.

Interagency Report Control No.: (b)(6), (b)(7)c

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0028

CUSTOMER NUMBER: 168

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

Bristol-Myers Squibb Combined
All Research and Development Site Report

Bristol Myers Squibb Company
P.O. Box 4000, (b)(2)High, (b)(7)f
Princeton, NJ 08543

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, research, 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	83	496	387	17	913
5. Cats	0	0	0	0	0
6. Guinea Pigs	1	108	583	0	691
7. Hamsters	0	68	415	0	483
8. Rabbits	0	169	1,775	6	1,950
9. Non-human Primates	512	391	308	8	707
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					
Gerbils	235	218	926	597	1,741

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

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

DATE SIGNED 11/13/08

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

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

Appendix #1

7023 Site Forms and Column E Explanations for 22-R-0028

October 1, 2007 - through September 30, 2008

Attachments
A #1, #2, #3
B
C
D

Pages - Series A-D

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 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

ANNUAL REPORT OF RESEARCH FACILITY

(b)(2)High, (b)(7)f

Bristol Myers Squibb Company
P.O. Box 4000 (b)(2)High, (b)(7)f
Princeton, NJ 08543

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

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A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, research, 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	0	73	9	1	83
5. Cats	0	0	0	0	0
6. Guinea Pigs	1	31	5	0	36
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	36	100	34	0	134
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 use.

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

SIGNATURE OF CEO.		NAL	DATE SIGNED
	(b)(6), (b)(7)c		11/13/08

APHIS FORM 7023
(AUG 91)

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

All redactions on this page are pursuant to (b)(4).

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 placed on test: 4

3. Species (common name): Canine (dog)

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

   One dog was used in an [redacted] study of a new pharmaceutical compound. The same compound had been previously studied in [redacted] rats, and [redacted] rabbits which resulted in changes in [redacted] that were not life-threatening and resolved within 2 hours. The magnitude of [redacted] changes in this untoward and unexpected death was not predictive from the previous studies in other species.

   The initial study was to consist of 4 dogs. After the initial dog showed adverse clinical signs (i.e. collapse), it was decided to discontinue the protocol. The one dog [redacted] died shortly (~ 20 min) after IV infusion of the compound.

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. [redacted] tests were performed in compliance with Good Laboratory Practice Regulations of the Food and Drug Administration (FDA).

   This animal listed above collapsed during the initial phases of the dosing period and died while it was being evaluated and prior to treatment.

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):

[redacted]

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 attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(b)(2)High, (b)(7)f

1. CERTIFICATE NUMBER: 22-R-0028

CUSTOMER NUMBER: 168

FORM APPROVED
OMB NO. 0579-0036

Bristol Myers Squibb Company
P.O. Box 4000, (b)(2)High, (b)(7)f
Princeton, NJ 08543

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, research, 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	13	110	186	2	298
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	279	48	6	333
9. Non-human Primates	0	39	133	0	172
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 use.

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

SIGNATURE (

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

DATE SIGNED

11/13/08

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

All redactions on this page are pursuant to (b)(4).

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 of animals placed on test: **40** .

3. Species (common name): **Dog**

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

   Both **dogs** included in column "E" were used in a [redacted] study of a new pharmaceutical compound. New pharmaceutical compounds administered by the [redacted] route elicited a range of side effects some adverse, such as [redacted] which are attributed to compound administration. One dog [redacted] died of a dosing accident. The other dog [redacted] died shortly (~10 minutes) after dosing with the compound on 28 June 08 and is considered drug related.

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. [redacted] 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 [redacted] 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):

   [redacted]

All redactions on this page are pursuant to (b)(4).

Special Use:

Column E Explanation

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1. Registration Number: **22-R-0028**

2. Number of animals placed on test: **111**

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

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

   Two (2) rabbits [redacted] included in category E were used in [redacted] study of a new pharmaceutical compound. New pharmaceutical compounds can elicit a range of side effects some adverse, such as [redacted] Both rabbits were found dead 1 March 08.

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. [redacted] 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 [redacted] 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):

   [redacted]

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 of animals placed on test: **30**

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

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

   The 4 rabbits [redacted] included in category E were used in [redacted] study of a new pharmaceutical compound. New pharmaceutical compounds can elicit a range of side effects some adverse, such as [redacted] All 4 rabbits were found dead from 25-29 March 08.

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. [redacted] 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 [redacted] 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):

   [redacted]

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 attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(b)(2)High, (b)(7)f

1. CERTIFICATE NUMBER: 22-R-0028

CUSTOMER NUMBER: 168

FORM APPROVED
OMB NO. 0579-0036

Bristol Myers Squibb Company
P.O. Box 4000, (b)(2)High, (b)(7)f
Princeton, NJ 08543

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, research, 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	12	0	45	0	45
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	56	578	0	634
7. Hamsters	0	45	415	0	460
8. Rabbits	0	96	1,727	0	1,823
9. Non-human Primates	341	65	46	0	111
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 use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

SIGNATURE (b)(6), (b)(7)c)NAL

DATE SIGNED 11/13/08

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

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UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(b)(2)High, (b)(7)f

1. CERTIFICATE NUMBER: 22-R-0028

CUSTOMER NUMBER: 168

FORM APPROVED
OMB NO. 0579-0036

Bristol Myers Squibb Company
P.O. Box 4000, (b)(2)High, (b)(7)f
Princeton, NJ 08543

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4. Dogs	0	14	41	0	55
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	21	0	0	21
7. Hamsters	0	23	0	0	23
8. Rabbits	0	0	0	0	0
9. Non-human Primates	1	12	82	0	94
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					
Gerbils	235	218	926	597	1,741

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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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)

SIGNATURE OF		ONAL	DATE SIGNED
	(b)(6), (b)(7)c		11/13/08

APHIS FORM 7023
(AUG 91)

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

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1. Registration Number: 22-R-0028

2. Number 597 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.

Five hundred ninety-seven gerbils were used in a study to assess the [redacted] compounds. Gerbils were dosed with test compounds either [redacted] after dosing, the gerbils were placed individually into a [redacted] For a period of [redacted] the gerbil's [redacted] which our ACUC wants to classify as distressful were evaluated and measured [redacted] Subjects were closely monitored during the study. At the conclusion of the study gerbils were euthanatized with carbon dioxide.

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

The use of analgesics or anesthetics to relieve the distress associated with this procedure would interfere with assessment of novel compounds for the treatment of [redacted] This behavioral paradigm is used to detect [redacted] and [redacted] which produce their [redacted] 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 N/A CFR N/A

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Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(b)(2)High, (b)(7)f

1. CERTIFICATE NUMBER: 22-R-0028

CUSTOMER NUMBER: 168

FORM APPROVED
OMB NO. 0579-0036

Bristol Myers Squibb Company
P.O. Box 4000, (b)(2)High, (b)(7)f
Princeton, NJ 08543

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, research, 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	58	196	13	14	223
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	14	0	0	14
9. Non-human Primates	134	175	13	8	196
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 use.

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

SIGNATURE OF CE(

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

NAL

DATE SIGNED
11/13/08

APHIS FORM 7023
(AUG 91)

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

All redactions on this page are pursuant to (b)(4).

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: **40** of animals used in this study.

3. Species (common name): **Beagle (Dog)**

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

   The **7** dogs used in a [redacted] study of pharmaceutical compounds at this site were included in Column E. New pharmaceutical compounds were administered to these animals by the [redacted] route. The **7** dogs in Column E experienced [redacted] on same day or [redacted] The 7 animals were sacrificed on the study day specified in the protocol.

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. [redacted] 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 [redacted] of the new pharmaceutical compounds being tested.

   Summary of Exemptions:

   There were no exceptions to USDA standards and regulations that applied to dogs during the reporting period.

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

   [redacted]

All redactions on this page are pursuant to (b)(4).

Column E Explanation

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1. Registration Number: **22-R-0028**

2. Number: **24** of animals used in this study.

3. Species (common name): **Beagle (Dog)**

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

   The **6** dogs used in a [redacted] study of pharmaceutical compounds at this site were included in Column E. New pharmaceutical compounds were administered to these animals by the [redacted] oute. The 6 dogs in Column E experienced pain due to [redacted] of short duration. 1 of the 6 dogs was found dead. 4 of the remaining 5 dogs were sacrificed prior to the end of study. The remaining dog was sacrificed on the study day specified in the protocol.

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. [redacted] 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 [redacted] of the new pharmaceutical compounds being tested.

   Summary of Exemptions:

   There were no exceptions to USDA standards and regulations that applied to dogs during the reporting period.

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

[redacted]

All redactions on this page are pursuant to (b)(4).

Column E Explanation

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1. Registration Number: **22-R-0028**

2. Number: **45** of animals used in this study.

3. Species (common name): **Beagle (Dog)**

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

   The **1** dog used in a [redacted] study of pharmaceutical compounds at this site was included in Column E. New pharmaceutical compounds were administered to this animal by the oral route. The 1 dog in Column E was euthanatized in moribund condition.

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

   These studies were conducted as part of a series of tests leading to potential further drug development in humans. [redacted] 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 [redacted] of the new pharmaceutical compounds being tested.

   Summary of Exemptions:

   There were no exceptions to USDA standards and regulations that applied to dogs during the reporting period.

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

[redacted]

All redactions on this page are pursuant to (b)(4).

Column E Explanation

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1. Registration Number: **22-R-0028**

2. Number: **20** of animals used in this study.

3. Species (common name): **Cynomologous (Monkey)**

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

   The **1** monkey used in a [redacted] study of pharmaceutical compounds at this site was included in Column E. New pharmaceutical compounds were administered to this animal by the [redacted] route. The 1 monkey in Column E died due to an error that occurred during gavage dosing.

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

   These studies were conducted as part of a series of tests leading to potential further drug development in humans. [redacted] 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 [redacted] of the new pharmaceutical compounds being tested.

   Summary of Exemptions:

   There were no exceptions to USDA standards and regulations that applied to dogs during the reporting period.

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

   [redacted]

All redactions on this page are pursuant to (b)(4).

Column E Explanation

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1. Registration Number: **22-R-0028**

2. Number: **40** of animals used in this study.

3. Species (common name): **Cynomologous (Monkey)**

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

   The **6** monkeys used in a [redacted] study of pharmaceutical compounds at this site were included in Column E. New pharmaceutical compounds were administered to these animals by the [redacted] route. The 6 monkeys in Column E had reduced [redacted] during the dosing period. The study director assessed these clinical signs to be distressful to the animals involved.

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. [redacted] 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 [redacted] of the new pharmaceutical compounds being tested.

   Summary of Exemptions:

   There were no exceptions to USDA standards and regulations that applied to dogs during the reporting period.

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

   [redacted]

All redactions on this page are pursuant to (b)(4).

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: **8** of animals used in this study.

3. Species (common name): **Cynomologous (Monkey)**

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

   The **1** monkey used in a [redacted] study of pharmaceutical compounds at this site was included in Column E. New pharmaceutical compounds were administered to this animal by the [redacted] route. The 1 monkey in Column E was humanely sacrificed due to a leg injury that occurred while on study.

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

   These studies were conducted as part of a series of tests leading to potential further drug development in humans. [redacted] 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 [redacted] of the new pharmaceutical compounds being tested.

   Summary of Exemptions:

   There were no exceptions to USDA standards and regulations that applied to dogs during the reporting period.

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

   [redacted]

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 attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(b)(2)High, (b)(7)f

1. CERTIFICATE NUMBER: 22-R-0028

CUSTOMER NUMBER: 168

FORM APPROVED
OMB NO. 0579-0036

Bristol Myers Squibb Company
P.O. Box 4000, (b)(2)High, (b)(7)f
Princeton, NJ 08543

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, research, 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	0	103	93	0	196
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	20	0	20
9. Non-human Primates	0	85	133	0	218
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 use.

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

SIGNATURE OF [redacted] NAL

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

DATE SIGNED
11/13/08

APHIS FORM 7023
(AUG 91)

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

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

Bristol-Myers Squibb Company

Pharmaceutical Research Institute

(b)(2)High, (b)(7)f

Supplement to the 2008 USDA Annual Report, APHIS Form 7023

Explanation of Animal Care and Use Committee Approved Exception to a USDA Standard

2-R-0028: Bristol-Myers Squibb Company, (b)(2)High, (b)(7)f

The (b)(2)High, (b)(7)f Animal Care and Use Committee has approved the following exception to USDA standards:

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

For 1-3 hours each day during dosing and feeding of the dogs and during cleaning of the runs, the beagles are placed in cages 22″ x 16⅜″ x 20⅜″ or larger. The dogs are fed individually in these cages so as to give each dog equal access to the diet. The temporary, separate housing also allows technicians to work with each animal on a one on one basis, collecting individual clinical observations and minimizing distress during dosing.

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

This exception was approved and in place for all (b)(2)High, (b)(7)f dogs listed on form 7023.