AMENDED REPORT

MAY 24 2010

SH

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED 0579-0036

This report is required by law (7 U.S.C. 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.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 41-R-0061

Customer Number: 15690

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

Wuxi Apptec Inc
2540 Executive Drive
St Paul, MN 55120

Telephone: (651) 675 2000

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*

WuXi Apptec Inc
2540 Executive Dr.
St. Paul, MN 55075

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 on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	1107	2434	14,844	9	17,287
7. Hamsters	0	0	0	0	0
8. Rabbits	56	414	① ~~3530~~ 3531	① ~~3~~ 2	3947
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual 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 provisions 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 (C.E.O.) or Legally Responsible Institutional Official (I.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

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

DATE SIGNED 5/21/10

APHIS F
AUG 200

①Wrong number. Upon review, it was discovered that only 2 rabbits should be Category E. KS 5/19/10

EXACT COPY
INITIALS KS DATE 10/29/09

NP 6/3/2010

SH

AMENDED REPORT

APHIS Form 7023 Site Addendum for FY: 2009

Registration Number: 41-R-0061
Customer ID Number: 15690

Facility Business Address Information:

Wuxi Apptec Inc
2540 Executive Drive
St Paul, MN 55120

Telephone: (651) 675 2000

Facilities Site(s) Address Information:

Site Code(s):

001
2540 Executive Drive
St Paul, MN 55120
Assigned Inspector: Debra Sime, D V M

NP 6/3/2010

AMENDED REPORT

MAY 2 4 2010

SH

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 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.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 41-R-0061

Customer Number: 15690

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

Wuxi Apptec Inc
2540 Executive Drive
St Paul, MN 55120

Telephone: (651) 675 2000

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary.)*

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 on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)

N/A KB 10/26/09

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 provisions 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 (C.E.O.) or Legally Responsible Institutional Official (I.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED

APHIS FORM 7023A
AUG 2009

EXACT COPY
INITIALS KB DATE 10/26/09

NP 6/8/2010

AMENDED REPORT

MAY 24 2010 SH

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: 41-R-0061

2. Number ①3 2 of animals used in this study.

3. Species (common name) New Zealand White Rabbit of animals used in the study.

4. Explain the procedure producing pain and/or distress.
The ①two ~~three~~ rabbits were used in a test titled "Bacterial Challenge Study in a Spinal Implant Model," IACUC Protocol 09-220. This was a custom study designed in conjunction with the sponsor. The procedure consisted of a rod and screw being implanted into the pelvis and then being dosed with bacteria. (S. aureus) The animals appeared normal until two days post-implant, when complications arose. The animals became extremely lethargic, hypothermic, lame and lost weight. They received supplemental food treats, subcutaneous fluids and were placed on warming pads. The rabbits died before they could be humanely euthanized.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)
The ①two ~~three~~ rabbits died with no pain or distress relief, before they could be humanely 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): NA

Agency _____ CFR _____

①wrong number. Upon review, it was discovered that 2 rabbits should be Category E. KS 5/19/10

EXACT COPY
INITIALS KS DATE 10/26/09

NP 6/3/2010

AMENDED REPORT

MAY 24 2010 SH

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: 41-R-0061

2. Number 4 of animals used in this study.

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

4. Explain the procedure producing pain and/or distress.
The four guinea pigs were used in a test titled "Guinea Pig Maximization Sensitization Test," NAMSA Protocol 98-02. This test is part of the preclinical biocompatibility evaluation of medical devices. This test is mandated by the US FDA and ISO 10993-1 and 10993-10. The animals are initially injected intradermally with test or control extract, Freund's adjuvant and/or saline. On Day 6, sodium lauryl sulfate mixed with mineral oil is topically applied. One animal was found dead prior to this. On Day 7, they undergo a topical application of test or control extract and are wrapped. Three guinea pigs were found dead in their respective cages 10 days after being unwrapped. All animals were necropsied by our veterinarian and tissues were evaluated by a histopathologist. Histopathologist findings were consistent with adenovirus pneumonia. No symptoms of illness were noted prior to death.

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 four guinea pigs died with no pain or distress relief. They were found dead in their cages.

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): See above

Agency _____ CFR _____

EXACT COPY
INITIALS FB DATE 10/26/09

NY 6/3/2010

AMENDED REPORT

MAY 24 20:) SH

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: 41-R-0061

2. Number 5 of animals used in this study.

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

4. Explain the procedure producing pain and/or distress.
The five guinea pigs were used in a test titled "In Vivo Assay for Viral Contaminants in Guinea Pigs, Adult and Newborn Mice- European," IACUC Protocol 99-25. This test is mandated as a safety screen by European regulatory agencies. The animals recieve injections of ~~test~~ or control material into the abdomen (IP) and muscle (IM). They are observed for 28 days. All five guinea pigs were found dead in their cages within a few days of each other and were all test animals. The root cause of death was identified as hydrothorax. No symptoms of illness were noted prior to death.

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 five guinea pigs were found dead in their cages.
No pain or distress relief was given.

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): See above

Agency _____ CFR _____

EXACT COPY
INITIALS KB DATE 10/24/05

MP 6/3/2010