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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: 22-R-0139

Customer Number: 35171

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

Sanofi Aventis
1041 Route 202-206, Mailstop Bw-K-303b
Bridgewater, NJ 08807

Telephone: (908) 231 2334

NOV 19 2009

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

FACILITY LOCATIONS (Sites) See Attached Listing

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress 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 | 21 | 71 | 0 | 0 | 71 |
| 5. Cats | 0 | 0 | 0 | 0 | 0 |
| 6. Guinea Pigs | 582 | 410 | 3153 | 8 | 3571 |
| 7. Hamsters | 0 | 0 | 0 | 0 | 0 |
| 8. Rabbits | 17 | 315 | 0 | 41 | 356 |
| 9. Non-human Primates | 0 | 12 | 33 | 12 | 57 |
| 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 (CEO) or Institutional Representative Official (IRO))

DATE SIGNED

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

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APHIS Form 7023 Site Addendum for FY: 2009

Registration Number: 22-R-0139
Customer ID Number: 35171

Facility Business Address Information:

Sanofi Aventis
1041 Route 202-206, Mailstop Bw-K-303b
Bridgewater, NJ 08807

Telephone: (908) 231 2334

Facilities Site(s) Address Information:

Site Code(s):

001

1041 Route 202-206

Bridgewater, NJ 08807

Assigned Inspector: Nadira Williams, V M D

002

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

Assigned Inspector: Joel Rubin, V M D

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USDA Annual Report
Registration #: 22-R-0139

Explanation of Category 'E' Animals

1. Number of Animals and Species Used in:

Pain Research

Used: 75 rabbits & 15 cynomolgus

Number of Category E animals: 40 rabbits & 11 cynomolgus

Early pharmacologic target validation

Used: 13 rabbits

Number Category E animals: 1

Respiratory Research

Used: 3210 guinea pigs, 53 cynomolgus

Number of Category E animals: 8 guinea pigs; 1 cynomolgus

2. Procedure Used:

Pain Alleviation Research

New medicines are needed to treat pain and help alleviate human suffering. Used in the testing of potential pain medications that shows no bioavailability in rodents. The model induces a focal area of superficial inflammation. A test medicine is then administered and a determination made as to whether or not it decreased inflammation. The rabbits are euthanized at the end of the one day study

The rabbits were used in the testing of potential pain medications that show no or little bioavailability in other species. The model induces a focal area of superficial inflammation. A test medicine is then administered and a determination made as to whether or not it decreased inflammation.

Early pharmacologic target validation model

These studies are required to evaluate potential effects of compounds on biologic receptors.

Respiratory Research

Guinea pigs and nonhuman primates are valuable animal models for the discovery and development of potential new medicines for the treatment of asthma.

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3. Justification for why pain and/or distress cannot be relieved:**Pain Alleviation Research**

Research compounds are tested as potential analgesics therefore no other analgesics or anesthetics can be used during the study. The cynomolgus monkeys were given analgesics and rabbits were humanely euthanized at the end of the study.

Development of an early pharmacologic target validation model

The animal died suddenly during experiment before veterinary care could be given.

Respiratory Pharmacology models for drug discovery

These guinea pigs were found dead during routine health checks the day of or the day following experiment. The administration of analgesic or anesthetic agents to these animals was not possible as the animals did not demonstrate any adverse clinical signs. The cynomolgus monkey died following a study, despite intensive veterinary medical care.

4. Procedure required by:

NA

5. IACUC Approved Exemptions:

Pharmacokinetic protocol has an exercise exemption for dogs while on radio-labeled studies.

JAN 19 2010

sanofi aventis
Because health matters

US R&D

January 14, 2010

Attn: Dr. Nicolette Petervary
United States Department of Agriculture
Animal and Plant Health Inspection Service
920 Main Campus Drive,
Suite 200, Unit 3040
Raleigh, NC 27606

Addendum to USDA Annual Report for sanofi-aventis US R&D 22-R-0139

Dear Dr. Petervary:

In response to your letter dated December 21st, 2009, the following information is provided as an addendum to the 2009 Annual Report.

Clarification Requested: Your facility's report listed dogs that were exempted from the exercise requirement. The reports, however, do not provide the numbers of dogs affected by the exception.

Clarification: A pharmacokinetic protocol has an exercise exemption for dogs while on radio-labeled studies. This exemption is in place to protect humans from excessive exposure to radioactivity. The excreta of the dogs are monitored weekly and as soon as the urine and feces reach a safe level, the dogs can again be exercised. The exemption ranged from 9 to 21 days. Six (6) dogs were affected in this reporting period.

Please contact me if you have further questions regarding the addenda. Thank you for your assistance in this matter.

Sincerely,

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