

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

43-R-0002

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)

SCIENTIFIC ASSOCIATES INC (Celsis Laboratory Group)

6200 S LINDBERGH BLVD

ST LOUIS, MO 63123

NOV 17 1999

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)

Biology Department
See Attached

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	---	---	---	---	---
5. Cats	2	0	41	0	41
6. Guinea Pigs	4	142	0	0	142
7. Hamsters	---	---	---	---	---
8. Rabbits	34	409	0	57	466
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).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11-11-99

ANNUAL REPORT OF RESEARCH FACILITY

Supplement

(E. "... explanation of the procedures producing pain or distress...and the reasons such (pain relieving) drugs were not used...")

1. Registration Number:

43-R-0003

2. Headquarters Research Facility

Celsis Laboratory Group (Scientific Associates)
St. Louis Division
6200 South Lindbergh Blvd.
St. Louis, MO 63123

During the period of October 1, 1998, through September 30, 1999, 57 rabbits were used in tests which were classified as causing pain or distress to the animals. Of these rabbits, 22 were used in antibody production studies involving the use of Freund's Complete Adjuvant. These animals did not appear to be in pain from the FCA use even though lesions did form on most rabbits. If animals had/have lesions present, we rinse their backs with warm sterile saline, but did not/do not provide any other pain relieving procedures.

Of the 57 rabbits mentioned above, 35 were used in pyrogen tests which we deemed as painful or distressing. (The pyrogen test, USP 23, p. 1718-1719; 21CFR Sections 436.32 and 610.13, does not allow for the administration of pain-relieving drugs due to their potential to interfere with the test.)

1. One rabbit was involved in a test which resulted in a death. About 15 minutes after being dosed, the rabbit kicked violently, settled down and then stopped breathing. Upon investigation, it was determined that the incorrect method for preparing the sample was submitted to us. Retesting of the correctly prepared sample showed no adverse affects in the animals.
2. 34 rabbits were involved in pyrogen tests involving a product that resulted in leaving raw skin exposed at the injection site (on the ear). It was also noted that if the sample was not fully injected intravenously, and infiltrated into the surrounding tissue of the ear, that necrosis of the injection area sometimes occurred.

Ensuring that injection needles are properly placed in the ear veins and no product drips onto the ear and that the injection site is properly occluded following the injection, assists in maintaining a healthy ear.

Written by:



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(b)(7)(C)

 11/9/99

Acknowledged by:



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switch
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