

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
22-R-0043

FORM APPROVED
OMB NO 0579-0038

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA
include Zip Code)
Celsis, Inc.
New Jersey Division
165 Fieldcrest Avenue
Edison, NJ 08837
Status: Active

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

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					
6. Guinea Pigs	14	541	-	58	599
7. Hamsters					
8. Rabbits	40	1089	36	42	1167
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 (b)(6) (b)(7)(C)	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) (b)(6) (b)(7)(C)	DATE SIGNED 12/1/99
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Celsis Laboratory Group

22R0043

November 30, 1999

Dr. Elizabeth Goldentyer
USDA, APHIS

New Jersey Division 920 Main Campus Drive, Suite 200, Unit 3040
165 Fieldcrest Avenue Raleigh, NC 27606
Edison, NJ 08837

Re: Attachment, Annual Report of Research Facility
Prepared and signed December 1, 1999

Registration Number: 22-R-004

Telephone

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Line 6 Number of animals upon which experiments, teaching, research, surgery or tests were conducted involving accompanying pain or distress to the animals and to which appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery or tests.

Guinea Pigs:

The procedure follows the standard protocol used by the industry and described in the literature (*). The animals received an injection of a 50% dilution of Freund's Complete Adjuvant, v:v.

The USDA has stated that the use of Freund's adjuvant may result in the presence of pain, distress or discomfort. No pain or distress was recorded for any of the animals used; however the resulting reaction may have created slight discomfort which could not be accurately measured. The use of drugs would have compromised the normal physiological animal reaction thereby jeopardizing the integrity of the study.

- Marzulli, F.N. and Miabach, H.I., *Dermatotoxicity*, third edition, 1987
- Magnusson, B. and Kligman, A.M., *Allergic Contact Dermatitis in the Guinea Pig*, 1970
- OECD-406

Rabbits:

The animals listed in section E were rabbits placed on Ocular or dermal irritation studies. The study procedures followed standard protocols used in industry. When reactions were evaluated that indicated more than momentary pain or distress to the animals, the studies were terminated.

The use of anesthetics/ analgesics would add an unknown variable or interfere with the test article and are not recommended by regulatory agencies.

Cc: [REDACTED]

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

DEC. 06 1999