

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 57-R-0023 CUSTOMER NUMBER: 880	FORM APPROVED OMB NO. 0579-0036
Lee Laboratories 1475 Athens Highway Grayson, GA 30221 Telephone: (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 animal 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 wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		714		2356	3070
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals	1	1			1
Chickens		70			70
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 rese 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 ap 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 inc 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) (b)(6), (b)(7)c	DATE SIGNED <i>11/7/08</i>
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BD Diagnostic Systems

Lee Laboratories
1475 Athens Highway
Grayson, GA 30017

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

www.leelabs.com

NOV 12 2008



Indispensable to
human health

November 7, 2007

Elizabeth Goldentyer, D.V.M.
USDA, APHIS Eastern Regional Office, Animal Care
Unit No. 3040
920 Main Campus Drive, Suite 200
Raleigh, NC 27606

Dear Dr. Goldentyer:

The 2,356 rabbits listed under Column E of our USDA Form 7023 were used to produce *Treponema pallidum* organisms for the diagnosis of syphilis. Under this IACUC approved protocol, number 4B, we infected rabbits with the organism, and allowed them to develop the disease for 10-12 days before euthanizing them. A post mortem harvest collected the *Treponema* spirochetes.

We may infer that the orchitis associated with *Treponema* infection caused some distress, but treatment of the disease would destroy or impact the organisms the procedure is intended to produce.

Sincerely,

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