This repor s required by law (7 USC 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 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-F-0025
CUSTOMER NUMBER: 12780

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

White Oak Animal Program
7519 Standish Place
Mpn4 Room 148
Rockville, MD 20855

Telephone: ~~(301) 827-4172~~ 240-276-9003

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 Atached 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 ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o 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		8	54	7	69
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 anestetic, 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)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
(b)(6),(b)(7)(c)	(b)(6),(b)(7)(c) 10/31/08

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T 88), which is obsolete.)

(AUG 91)

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USDA Column E Explanation

Reporting Year October 1, 2007 - September 30, 2008

Certificate Number / Customer Number : 51-F-0025 / 12780

A total of 27 NZW rabbits were used in this study. Only 7 of the 27 were in USDA Column E Category.

The study was to evaluate the inflammatory response of the rabbit eye to an intercameral injection of bacterial endotoxin and to determine the level of endotoxin for a threshold inflammatory response. The results of the study will be used to support the development of endotoxin limits for intraocular devices for human use. The rabbit has been reported in literature to develop a febrile response similar to that of the human upon IV exposure to bacterial endotoxin and is the animal model specified in the US Pharmacopeia for pyrogen testing. Since the objective of the study was to determine the concentration of endotoxin to produce a threshold inflammatory response, the use of any medications other than prophylactic topical antibiotics would confound study findings. The rabbits in the two highest doses were expected to develop a moderate to severe inflammatory reaction. The inflammation uveitis, generally manifests as cells, flare, and sometimes fibrin. The PI was a ophthalmologist who is experienced in uveitis, pain medication is not typically given to human patients for uveitis. However, the discomfort (and inclusion in USDA Category E) derives from ciliary spasm, most prominent when the pupil reacts in response to light. The more severe the uveitis, the higher probability of ciliary spasm in the treated eye when exposed to light for examination after dosing.