This report is 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!

NOV 2 8 2008

See attached form for additional information.

Interagency Report Control No:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 51-R-0036
CUSTOMER NUMBER: 93

FORM APPROVED
OMB NO. 0579-0036

Bioqual Inc
9600 Medical Center Drive
Rockville, MD 20850

Telephone: (301) -251-0633

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 reasc 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		16			16
7. Hamsters					
8. Rabbits	4	576	12	2	590
9. Non-human Primates	77	944	800		1744
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets			397		397

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)

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

DATE SIGNED 11/26/08

Nf

Column E Explanation

1. **Registration Number:** 51-R-0036

2. **Number** __12_____ **of animals used in this study**

3. **Species (common name)** ___Rabbit____**of animals used in the study**

4. **Explain the procedure producing pain and/or distress.**

   The study was an initial toxicity study where rabbits were treated sequentially with increasing doses to determine acute toxicity of a test article. The main focus of an acute toxicity study is to observe the symptoms and recovery of the animals following administration of a single high dose. None of the rabbits in the control, low and mid dose groups exhibited any pain or distress. Two rabbits in the high dose group exhibited signs of toxicity within 8-12 hours after dosing. The rabbits were examined by the attending veterinarian. Considerable improvement in their condition was observed 24 hours after dosing, and both rabbits appeared normal, including a return to normal appetite, by day 7 of the study.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

   The data from acute toxicity studies are used to identify target organs and dose selection for repeated dose toxicity studies. In addition, information gathered from these studies provides relevant information on acute overdosing in humans. In this regard, inclusion of pain medication interferes with the observation of clinical signs of toxicity and the toxicity endpoints of the study. An important goal of this study is to determine if the animal is capable of clearing the drug and surviving. Judgements regarding euthanasia incorporated the expert opinions of the personnel involved in the study, including the attending veterinarians, and followed the guidelines for humane endpoints as described in the OECD guidance (Nov. 2000).

Summary of exemptions for BIOQUAL, Inc.

Registration Number: 51-R-0036

Date: 11/26/08

An exemption to the cage changing schedule was requested for a BSL3 study. Due to space constraints in the BSL3 suite it was anticipated that the study would require the animals to remain in the BSL3 suite for longer than the approved 14 days without a cage change. The BSL3 personnel would clean the inside of the cages daily during the study period. The BIOQUAL IACUC approved this request. The exemption was not necessary as the study ended within the approved 14 day cage changing schedule.