This report is required by law (7 USC 21 43) 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 2160

Set reverse side for additional information

Interagency Report Control No 0580-0004-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 21-R-0209 #30934

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)

Ethicon Inc
(b)(2)High, (b)(7)f
1934 Lever Park Lane
Salt Lake City, Utah 84123 Ph 801-264-1001

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.)

(b)(2)High, (b)(7)f

Revision 6.2.2010

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 production, 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		1125	0	1996	3121
7. Hamsters					
8. Rabbits	28	1063	723	11	1397
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 CEO OR RESPONSIBLE OFFICIAL (b)(6), (b)(7)c

(Type or Print)

DATE (SIGNED) June 2, 2010

(AUG 91)

NP 6/4/2010

Annual Report Addendum, 10/1/2008 to 9/30/2009, Facility No. 21-R-0209
Category E Explanation-Guinea Pigs

The Guinea Pig Maximization (Sensitization) Test is a procedure which determines the allergenicity of materials. This study is required by the FDA Modified ISO 10993-1 matrix for preclinical evaluations of Class II and III medical devices. In this procedure, an adjuvant and extract are injected intradermally. The adjuvant enhances the immune response and does result in lesion formation at the injection site. These lesions, ranging in size from 3mm to 20mm, are not treated due to the possible interference or enhancement of the sensitization response. In order to determine the health status of these animals, daily observations are performed and animal health technical personnel evaluate the sites. Any abnormal findings are reported to the Attending Veterinarian for assessment. During this period none of the 1996 guinea pigs used in this evaluation (defined as Category E) required additional veterinary care for problems related to the lesions.

In order to address pain and distress, the Attending Veterinarian researched analgesics and an appropriate oral medication which would not affect the animals' fluid intake was not available. The nature of the Guinea Pig Maximization Test negates the use of topical analgesia. We also performed weight trends and the animals exhibited weight gain throughout the test procedure. The animals ambulated normally and only vocalized when handled (as is the case with untreated guinea pigs).

Category E Explanation-Rabbits

Two rabbits which were categorized in "E" were evaluated in the ISO Ocular Irritation Test. This test is required by FDA for compliance with the ISO 10993 Biocompatibility Standard. Due to the nature of the evaluation, i.e. the testing of medical devices and associated products (in this case, contact lenses and associated solutions), significant reactions are not expected. However should reactions occur, we have incorporated a scoring procedure which provides a tool for assessing the potential of pain and distress. Out of approximately 300 animals evaluated in this program, 2 exhibited scores which were above the limit. These animals were immediately euthanized. Analgesia can not be administered during the study because of potential interference with the grading. Eight rabbits which were categorized in "E" were evaluated in the ISO Primary Skin Irritation Test. This test is required by FDA for compliance with the ISO 10993 Biocompatibility Standard. Due to the nature of the evaluation, i.e. the testing of medical devices and associated products, significant reactions are not expected. However should reactions occur, we have incorporated a scoring procedure which provides a tool for assessing the potential of pain and distress. Out of approximately 250 animals evaluated in this program, 8 exhibited scores which were above the limit of 2/2. After study completion (no more than 72 hours) the animals were either euthanized or given Banamine for pain relief. One animal was involved in a research study evaluating a drug formulation for treatment of keratoconjunctivitis sicca. The dosage of the research drug was incorrect resulting in animal death before intervention could occur.

NP 6/4/2010