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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!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 21-R-0209
CUSTOMER NUMBER: 30934

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Ethox Corp
Sts Duotek
251 Seneca St
Buffalo, NY 14204

Telephone: (716) -842-4000

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					0
5. Cats					0
6. Guinea Pigs	51	832	0	2399	3231
7. Hamsters					0
8. Rabbits	45	549	508	9	1066
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					0

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

NP

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Annual Report Addendum, 10/1/2007 to 9/30/2008, 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 2,395 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).

The Japanese Antigenicity Test is defined in the standard set forth in the Japanese Pharmacopeia and is required for the quality control release of biologics based on the Japanese regulations. This evaluation determines the allergenicity of the test material though several exposures. A positive control is required which results in an extreme allergic response. One test was performed during this time period using 4 animals for the positive control assessment. Animals were immediately euthanized at study completion which was within 24 hours after exposure to the challenge. Analgesia can not be administered during the study because of potential interference with allergic response/toxicity.

Category E Explanation-Rabbits

Six 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 497 animals evaluated in this program, 6 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.

Three rabbits which were categorized in "E" were evaluated in the Rabbit Pyrogen Test, required for release of medical devices and pharmaceuticals for a non-pyrogenic label claim and for material mediated pyrogen assessment in accordance with ISO 10993-1. Due to the nature of the evaluation, i.e. the testing of medical devices and biologics, significant temperature increases are not expected. However should an animal exhibit a rectal temperature of 41 degrees C or greater, the animals will be administered Banamine to reduce their fever. Over 500 tests were performed (with at least 3 animals per test) and 3 animals required intervention with Banamine at study completion. Administration of a fever reducing agent during the test is contraindicated as it will interfere with the study objective.