Th' ; 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

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 33-R-0113
CUSTOMER NUMBER: 707

FORM APPROVED
OMB NO. 0579-0036

Southern Illinois University School Of Medicine
Division Of Lab Animal Med
825 N Rutledge St Po Box 19611
Springfield, IL 62794

Telephone: (217) -545-3053

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			51	22	73
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs			8		8
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)

S [redacted] (b)(6), (6)(7)(C)

[redacted] (b)(6), (6)(7)(C)

DATE SIGNED 11.19.08

AF [redacted] obsolete.)

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Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 33-R-0113

2. Number 22 of animals used in this study.

3. Species (common name) guinea pigs of animals used in the study.

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

Twenty-two guinea pigs were used on a positive control skin sensitization test. Animals received varying dosages topically of hexyl cinnamic aldehyde once to three times per week for 3 weeks and then were challenged two times after a two week rest period. A small number of animals had reddened skin on the area of application and at the challenge site. No animals exhibited skin swelling or severe skin reactions and all animals appeared normal otherwise. Although animals were classified in the Category E, animals exhibited minor clinical signs during the study and were not considered to have experienced pain and distress.

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. (For Federally mandated testing, see Item 6 below)

The study was designed for commercial product testing. It examined the potential of the product to cause sensitization or allergic responses. This study was designed in accordance with regulatory guidance documents. The guinea pig was selected as it is the most common species used in skin sensitization testing for compounds intended for clinical use. Toxicity testing is the method used to examine the potential effects of compounds and/or formulations developed for clinical use. This study examined the potential to cause skin sensitization after multiple occluded exposures. Study design was such to maximize the exposure potential. The medical benefit would be a potentially wider acceptance and use of a formulation that has the probability of low toxicity and side effects. The positive control group was included to ensure the testing has been conducted accurately.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency OECD CFR OECD Guideline for Testing of Chemicals 406: Skin Sensitization

EPA Health Effects Test Guidelines: OPPTS 870,2600 Skin Sensitization

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