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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 31-R-0016 31R0016

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

222

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Springborn Laboratories, Inc.
640 N. Elizabeth Street
P.O. Box 143
Spencerville, OH 45887-0143
Status: Active

NOV 17 1999

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.)

FACILITY LOCATIONS *(Sites)*

~~Same As Above~~ Springborn Laboratories, Inc.	Springborn Laboratories, Inc.
553 N. Broadway, Spencerville, OH 45887	640 N. Elizabeth St., Spencerville, OH 45887

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 procedures, 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		382		6	388
5. Cats					
6. Guinea Pigs		4271		8	4279
7. Hamsters		135			135
8. Rabbits	2	2317		33	2350
9. Non-human Primates					
10. Sheep					
11. Pigs		32			32
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
[redacted] (b)(6) (b)(7)(C)	[redacted] (b)(6) (b)(7)(C)	11/15/99

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

31R0016

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Springborn Laboratories, Inc. (31-R-0016)

Section E.8

Thirty-three rabbits experienced very brief discomfort resulting from test article administration during preclinical toxicology testing. These animals were used on acute dermal toxicity (27 rabbits), and primary eye irritation (6 rabbits) studies. These studies are required by the U.S. EPA Hazard Evaluation Guidelines and the U.S. FDA Guidelines for development of human safety data.

For the primary eye studies, the ocular tissue is not anesthetized since inhibition of the blink and/or tear response may alter the experimental results. In addition, the local anesthetic agents may interact with the test article altering the ocular response. Some local anesthetics can also cause loss of the surface cells of the cornea and delay corneal epithelial regeneration.

The dermal toxicity studies were conducted to monitor several endpoints, including clinical effects, body weight effects, lethality and reversible toxicity. Since lethality and reversible toxicity are specific endpoints in these evaluations, administration of sedatives, tranquilizers and/or analgesics could interfere with these endpoints. If no mortality is produced by administration of a specific dose level, no further testing is required under the guidelines, thus eliminating unnecessary animal testing.

Eight guinea pigs experienced distress following test article administration and were euthanized for humane reasons. Pain-relieving drugs would have interfered with the purpose of the dermal sensitization study required by the FDA Center for Drug Evaluation and Research for development of human safety data.

Six dogs experienced brief discomfort following test substance administration. The discomfort for three of the dogs was minimal and of short duration. The remaining three dogs were euthanized for humane reasons because analgesics would have interfered with the purpose and/or results of the study. The studies were required by the FDA for development of human safety data.