

22R0010

USDA Annual Report - 1999  
Cyanamid Foundation for Agricultural Development  
Registration Number 22-R-0010

NOV 15 1999

#### Explanation of Column E Entry

The 30 rabbits listed in Column E were used for ocular irritation studies. These studies were performed using the Guidelines published in the Federal Register, 43 FR 37336, part 163-81-4 (ocular irritation). The data provided by these studies is used to evaluate the toxic and irritant potential of novel proprietary compounds. This information is an integral part of the product submission packets provided to federal and foreign governmental agencies.

The concurrent administration of other chemicals, including analgesic and anesthetic compounds, to the test animals has the potential to mask or alter adverse signs. In addition, the administration of other chemicals might interact with the test articles. Either effect would interfere with the proper evaluation of the test results.

The criteria used to determine column E entry is based on the Draize<sup>1</sup> scoring system. Any animal in a primary eye irritation study that has a score of 3 or more for either corneal opacity or conjunctival irritation (redness or swelling, discharge is excluded) and/or an iris score of 2 at anytime during the course of the study are placed in column E.

These studies were reviewed and approved by the Institutional Animal Care and Use Committee.

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<sup>1</sup> Draize, H.J., Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, Assoc. of Food and Drug Officials of the United States, 3<sup>rd</sup> Printing, 1975, page 51.

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0012

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.

P.O. BOX 151

SOMERVILLE, NJ 08876-0151

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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)

ETHICON, INC.

P.O. BOX 151

SOMERVILLE, NJ 08876

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	0		3*		3
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	18		50*		50
9. Non-human Primates					
10. Sheep					
11. Pigs			431*		431
12. Other Farm Animals					
13. Other Animals					
NOTE: *	3 Dogs.	6 Rabbits	420 Pigs were	involved in terminal operative	
	procedures.				

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 C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

12/1/99