

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. 93-R-0025
CUSTOMER NO. 1184

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)

CALIFORNIA DEPT. OF HEALTH SERVICES
850 MARINA BAY PARKWAY, ROOM B153
ANIMAL CARE AND USE PROGRAM
RICHMOND LABORATORIES CAMPUS
RICHMOND CA 94804

(b)(6), (b)(7)(c)

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)

See Attached Listino

(b)(2)High, (b)(7)(F)

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-
5. Cats					-0-
6. Guinea Pigs					-0-
7. Hamsters	34	12	-0-	15 (explanation .	27
8. Rabbits				attached)	-0-
9. Non-Human Primates					-0-
10. Sheep					-0-
11. Pigs					-0-
12. Other Farm Animals					-0-
13. Other Animals (Laboratory-bred mice of the genus Mus, only.)					

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 the 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.

NOV 13 2006

RTIFICATION 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)

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

DATE SIGNED

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IM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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Column E Explanation

Facility Registration Number: 93-R-0025
Customer Number 1184

One Column E study using hamsters: Thirty three hamster pups were dosed with botulism spores; fourteen died or were symptomatic including two that were cannibalized by their mother which also died. All of these including that mother are counted in Col. E since she was affected by the experiment although not purposefully dosed. The unaffected mothers of other litters are counted in Col. C as are pups which were dosed but did not become symptomatic or die.

Description/explanation/purpose of study: The investigator is attempting to develop a model for human infant botulism in which the intestinal tract becomes colonized with *Costridium botulium* using infant hamsters intragastrically inoculated with botulism spores.

Scientific or regulatory justification for withholding of pain distress relief:

Botulism produces paralysis, including respiratory paralysis, but not pain. A Medline search provided evidence that paralysis and respiratory distress in humans while not painful, is distressing. Although infant hamsters are neurologically immature at the seven day age of inoculation, we assumed that some distress may still occur.

For infant hamsters respiratory depression is the principal clinical sign of botulism toxicosis. Thus, a drug which causes any degree of respiratory depression would inhibit recognition of toxicosis. Additional search of the literature revealed that all presently known or available classes of drugs including anesthetics, analgesics, tranquilizers, and anxiolytics produce respiratory depression as a side effect. The investigator and the IACUC determined that no drugs were presently available which could counteract suspected distress without jeopardizing the outcome of the experiment.

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California Department of Health Services
Attachment to Annual Report (USDA Form 7023) for FY 2006
Facility Registration Number: 93-R-0025
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Summary of Exceptions to the Regulations and Standards Approved by the IACUC:

NONE

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