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WASHINGTON BIOTECHNOLOGY, INC.

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Explanation for Column E (Annual Report of Research Facility)

The guinea pigs counted in this column were used in quality control tests to evaluate protection provided by a human vaccine against diphtheria and tetanus. The tests are routinely carried out according to FDA requirements for batch release of product intended for human use.

We perform this test according to our Protocol No. 1200. A copy of page 1 of this protocol is attached for information.

A literature search has been carried out to evaluate alternative procedures. The results of this search are available as an appendix to Protocol No. 1200. One result of the search has been to justify reduction in the number of animals used per assay.

Our Protocol No. 1200 is available for inspection and has been inspected by USDA inspectors on several visits to our facility.

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.

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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.

42-R-0020

FORM APPROVED
OMB NO. 0579-0036

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

Grand Laboratories, Inc.
1447 140th St.
ATTN: Ralph L. Pierce
Larchwood, Iowa 51241

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

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 item #2.

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					
5. Cats					
6. Guinea Pigs				2	
7. Hamsters					
8. Rabbits			1,982		1,982
9. Non-human Primates					
10. Sheep		2			2
11. Pigs		234			234
12. Other Farm Animals					
Calves		12			12
13. Other Animals					
Mice		19,660		5,496	25,156
Chickens		6			6

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 HEADQUARTES 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

b6, b7c

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

b6, b7c

DATE SIGNED

10/28/99