

T.T. 10/23/05

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 84-R-0007
CUSTOMER NUMBER: 1080

FORM APPROVED
OMB NO. 0678-0041

*A by B. Bederson
10/23/05*

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Colorado Serum Company
4950 York Street
Denver, CO 80216

Telephone: (303)-295-7527

COPY FOR YOUR INFORMATION

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 Attached 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 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, 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 | 16 | 628 | 124 | 950 | 1702 |
| 7. Hamsters | 107 | 770 | 0 | 431 | 1201 |
| 8. Rabbits | 1 | 0 | 107 | 0 | 107 |
| 9. Non-human Primates | - | - | - | - | - |
| 10. Sheep | - | - | - | - | - |
| 11. Pigs | - | - | - | - | - |
| 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 anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, 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)

| | | | |
|-----------------------------------|-------------------------------|--|-----------------------------|
| SIGNATURE (b)(6),(b)(7)(c) | TITLE (b)(6),(b)(7)(c) | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) (b)(6),(b)(7)(c) | DATE SIGNED 10-13-05 |
|-----------------------------------|-------------------------------|--|-----------------------------|

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Throughout this year, provisions in 9CFR 117.4(e) were applied to all animals in tests conducted according to 9CFR 113.451(b), 9CFR 113.106(c), 9CFR 113.101(c), 9CFR 113.102(c), 9CFR 113.103(c), and 9CFR 113.104(c).

In each test guinea pigs or hamsters that showed clinical signs of illness due to the test were humanely destroyed if the illness progressed to the point when death was certain to occur without therapeutic intervention.

Regarding another matter, we are requesting that our address used on future inspection reports be changed to use our P.O. Box 16428 instead of 4950 York Street.

Please contact us if there are any questions.

Sincerely,

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

Encl.

Colorado Serum Company
License No. 84-R-0007

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For FY 2004-2005 Annual Report of Registered Research Facility

Each animal in each referenced test was employed in testing a Licensed Veterinary Biological product as required by Federal Regulations as codified in Title 9CFR. Humane euthanasia of animals on 9CFR required tests is provided for in 9CFR 117.4(e) – Animals at licensed establishments – test animals (filed August 18, 1995). This is included as standard testing protocol. While limiting the duration of the pain and distress it does not fulfill the description of use as described treatment in Section D of APHIS Form 7023, page 1. Therefore, we feel obligated to continue to include these test animals in Section E.

Attending veterinarians and related employees have been informed and Colorado Serum Company is complying with this provision.

Explanation of usage of animals listed in Column E.

Line Item 6.

Guinea Pigs

950 guinea Pigs were tested causing pain, for which no anesthetic, analgesics, or tranquilizers could be used. A detailed breakdown of guinea pigs by test reference is provided.

9CFR 113.451(b) Tetanus Antitoxin potency testing – 922 guinea pigs.

Humane endpoints were addressed for all animals on this test thus reducing the duration of pain and suffering.

9CFR 113.106(c) Clostridium chauvoei Bacterin potency testing – 28 guinea pigs.

Humane endpoints were addressed for all animals on this test thus reducing the duration of pain and suffering.

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Line Item 7. Hamsters

431 Hamsters were tested causing pain, for which no anesthetics, analgesics, or tranquilizers could be used. A detailed breakdown of hamsters by test reference is provided.

9CFR 113.101(c) Leptospira Pomona Bacterin potency testing – 88 hamsters.

The 88 hamsters included required controls for potency tests (9CFR 113.101(c)(2)) plus necessary hamsters required to establish the validity of the challenge dose (10 to 10,000 hamster LD₅₀) by titration. 9CFR 113.101 (c)(3).

For all test hamsters, Colorado Serum Company specifically has applied provisions of 9CFR 117.4(e) wherein ill animals were humanely euthanized upon reaching a point where death was expected to occur.

9CFR 113.102(c) Leptospira Icterohaemorrhagiae Bacterin potency testing – 118 hamsters.

The 118 hamsters included required controls for potency tests (9CFR 113.102(c)(2)) plus necessary hamsters required to establish the validity of the challenge dose (10 to 10,000 hamster LD₅₀) by titration. 9CFR 113.102(c)(3).

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Line Item 7. continued

9CFR 113.102(c) continued

For all test hamsters, Colorado Serum Company specifically has applied provisions of 9CFR 117.4(e) wherein ill animals were humanely euthanized upon reaching a point where death was expected to occur.

9CFR 113.103(c) Leptospira Canicola Bacterin potency testing – 120 hamsters.

The 120 hamsters included required controls for potency tests (9CFR 113.103(c)(2)) plus necessary hamsters required to establish the validity of the challenge dose (10 to 10,000 hamster LD₅₀) by titration. 9CFR 113.103(c)(3).

For all test hamsters, Colorado Serum Company specifically has applied provisions of 9CFR 117.4(e) wherein ill animals were humanely euthanized upon reaching a point where death was expected to occur.

9CFR 113.104(c) Leptospira Grippotyphosa Bacterin potency testing – 105 hamsters.

The 105 hamsters included required controls for potency tests. (9CFR 113.104(c)(2) plus necessary hamsters required to establish the validity of the challenge dose (10 to 10,000) hamster LD₅₀) by titration. 9CFR 113.104(c)(3).

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Line Item 7. continued

9CFR 113.104(c) continued

For all test hamsters, Colorado Serum Company specifically has applied provisions of 9CFR 117.4(e) wherein ill animals were humanely euthanized upon reaching a point where death was expected to occur.

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

10-13-05

Date

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