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OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 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.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

REGISTRATION NUMBER: 51-R-0082

Customer Number: 33766

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

Bioreliance Corporation
14920 Broschart Road
Rockville, MD 20850

Telephone: (301) 738 1000

DEC 03 2009

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) 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 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 on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		192	1933		2125
7. Hamsters		768	465	265	1498
8. Rabbits		100			100
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, 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 provisions 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 (C.E.O.) or Legally Responsible Institutional Official (L.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR L.O.	NAME AND TITLE OF C.E.O. OR L.O.	DATE SIGNED
(b)(6), (b)(7)c		11/30/09

SG 12-4-09

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column e explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-R-0082
2. Number of animals used in this study. 120-228 per study based on study design

Studies:

AC10HB.195340.BSV - 37 hamsters

AC10HF.195341.BSV - 37 hamsters

AC20FD.195343.BSV - 110 hamsters

AC20NG.195342.BSV - 81 hamsters

3. Species (common name): Hamster
4. Explain the procedure producing pain and/or distress.

The pain experienced is due to the development of scrapie clinical signs in hamsters. The In Vivo assay is currently the most sensitive assay for scrapie and the only method accepted by regulatory agencies for scrapie. Regulatory agencies are requiring that manufacturers show the efficacy of their manufacturing process in the removal of possible contaminants. Animals must be held until the terminal stage of the disease is observed. All clinical signs must be confirmed histopathologically.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (for Federally mandated testing, see below)

See 6. below.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g, APHIS, 9 CFR 113, 102).
 - a. “Federal Bulletin No. 40, 26 February 1994, German Federal Ministry of Health Guidelines on Safety Measures for Minimizing the Risk of transmission of BSE and Scrapie”.
 - b. “WHO Consultation of Medical and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies” (Geneva 24-26, March, 1997) and OIE Animal Health Code (May 1997) Concerning BSE.
 - c. Committee for Proprietary Medicinal Products (CPMP) “Notes for Guidance Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products”, (1997).