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 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

AMENDED

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 23-R-0061
CUSTOMER NUMBER: 352

FORM APPROVED
OMB NO. 0579-0036

Millennium Bioresearch Inc
1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18967

Telephone: (215) -536-4110

RECEIVED
FEB 12 2009
BY

3. 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 Atached 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 ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o 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 an 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 wh the use of appropriate anesthetic, analgesic, or tranquiliz 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	62	862	0	238	1100
7. Hamsters					
8. Rabbits	74	909	3	396	1308
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
FERRETS	0	3	0	21	24
PIGS	0	6	9	0	15

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
(b)(6), (b)(7)(c)		2-10-09

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

NF

MB Research Laboratories

FEB 1 2 2009

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COLUMN E EXPLANATION - 2008
Facility Registration No: 23-R-0061

Guinea Pigs: The two hundred thirty-eight guinea pigs listed in Column E were used on Magnusson-Kligman sensitization evaluations, as described in OECD testing guideline regulations. The Magnusson-Kligman is the favored guinea pig sensitization assay in Europe over the less invasive Buehler method and is used by sponsors pursuing a global market for their product. The purpose of this study is to assess the sensitization potential of a substance following repeated dermal exposure. The initial inductions used for these studies involve the use of Freund's Complete Adjuvant injections which produce an irritant response. This is a regulatory driven protocol and there are no provisions in the test guideline to permit the use of analgesia or anesthetics. The citing for this test guideline is as follows:

- Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals, Guideline #406, Skin Sensitization, Adopted by the Council on July 17, 1992.

Currently, the Local Lymph Node Assay (LLNA) using mice is an accepted method for sensitization studies. However, this study requires the radioactive procedures. In 2002, MB was awarded a Small Business Innovative Research (SBIR) Phase II grant for the development and commercialization of a Local Lymph Node Assay using mice but eliminating the need for radioactive procedures. This Phase II research has been successfully completed. MB Research is currently conducting these studies for commercial clients. However, the regulatory agencies, i.e., FHSA, EPA, OECD, have not yet adopted this LLNA version as an approved test guideline for sensitization studies, so it cannot be used as an alternative to either the Magnusson-Kligman or Buehler Methods.

Rabbits: The three hundred ninety-six rabbits listed in Column E of the Annual Report were used in EPA, OECD or FHSA dermal or ocular irritation/corrosion studies and dermal toxicity studies in which the use of anesthetics has the potential to mask or worsen the responses being investigated. The purpose of these studies is to determine the irritant or corrosive effect of a substance when applied to the skin or eye. In cases where there is reason to believe that ocular or dermal reactions may be severe, MB recommends to the study sponsor that only one rabbit be tested. In cases where the reaction is severe, the sponsor is notified and the animals are humanely sacrificed to avoid further distress. The citings for these studies are as follows:

- OECD Guidelines for Testing of Chemicals:
  - Guideline #402, Acute Dermal Toxicity in Rabbits, Adopted February 24, 1987
  - Guideline #404, Acute Dermal Irritation/Corrosion, Adopted by the Council April 24, 2002
  - Guideline #405, Acute Eye Irritation/Corrosion, Adopted by the Council on April 24, 2002
- EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS), Health Effects Test Guidelines:
  - Guideline #870.2400, Acute Eye Irritation, effective August 1998
  - Guideline #870.2500, Acute Dermal Irritation, effective August 1998
  - Guideline #870.1200, Acute Dermal Toxicity, effective August 1998
- FHSA - Federal Hazardous Substance Act
  - 16 CFR 1500.40, Acute Dermal Toxicity
  - 16 CFR 1500.41, Primary Dermal Irritation
  - 16 CFR 1500.42, Primary Eye Irritation

Ferrets: Twenty-one ferrets listed in Column E were used on acute and delayed emesis studies for the purpose of evaluating emetic response. These studies are necessary in order to determine if ingestion of a specific drug or compound will result in an emetic reaction. Non-animal models are not appropriate for this type of study because the central nervous system is integral to the emetic response. Less sentient species are not useful, e.g., the rat does not have an emetic response. Currently, there are no viable alternative methods for evaluation of this response. In case of severe vomiting (greater than 20 minutes), acepromazine is administered.

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

Millennium BioResearch Inc.,(dba/MB Research Laboratories)