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

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 31-R-0091
CUSTOMER NUMBER: 254

FORM APPROVED
OMB NO. 0579-0036

Ricerca Biosciences Llc
7528 Auburn Road
Concord, OH 44077

Telephone: (440) -357-3300

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 necesarv 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 tranquilz 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	20	557	115	19	691
5. Cats	2	12	0	0	12
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	20	0	48	0	48
8. Rabbits	21	8	80	0	88
9. Non-human Primates	78	83	65	0	148
10. Sheep	0	0	0	0	0
11. Pigs	0	13	0	0	13
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

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		11/19/08

APHIS FORM 7023 (Replaces VS FORM 19-23 (OCT 88), which is obsolete.)
(AUG 91)

NOV 2 4 2008

Column E Explanation

1. Registration Number: 31-R-0091

2. Number of animals used in this study: 32, of which 17 were considered to experience unrelieved pain or distress.

3. Species (common name) of animals used in this study: Dog

4. Explanation of the procedure producing pain/or distress:

Administration of the test article in the 14-day oral toxicity study caused pain or distress in 17 dogs.

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 Item 6 below)

The purpose of this study was to define the oral toxicity and if signs of toxicity were alleviated or treated the goal of the study could not be achieved.

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.

FDA 21 CFR 312 and FDA 21 CFR 58

Column E Explanation

1. Registration Number: 31-R-0091

2. Number of animals used in this study: 40, 1 animal found dead.

3. Species (common name) of animals used in this study: Dog

4. Explanation of the procedure producing pain/or distress:

1 animal found dead in cage the morning following administration of test article.

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 Item 6 below)

Death occurred during evening hours when observations were not performed. There was no indication of a problem during earlier scheduled and unscheduled observations.

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.

FDA 21 CFR 312 and FDA 21 CFR 58

Column E Explanation

1. Registration Number: 31-R-0091

2. Number of animals used in this study: 4, of which 1 animal died

3. Species (common name) of animals used in this study: Dog

4. Explanation of the procedure producing pain/or distress:

Dosing of compound

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 Item 6 below)

1 animal died prior to treatment

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.

FDA 21 CFR 312 and FDA 21 CFR 58