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: 93-R-0512
CUSTOMER NUMBER: 39987

FORM APPROVED
OMB NO. 0579-0036

Explora Biolabs, L L C
1155 Camino Del Mar, #535
Del Mar, CA 92014

Telephone: (858) -273-6574

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 reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	2			78	78
5. Cats	—				
6. Guinea Pigs			76		76
7. Hamsters	—				
8. Rabbits			61		61
9. Non-human Primates	—				
10. Sheep	—				
11. Pigs	—				
12. Other Farm Animals	—				
13. Other Animals					
Ferrets	4				—

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)

NOV - 6 2008

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

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) (b)(6),(b)(7)(c)

DATE SIGNED

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)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

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:** 93-R-0512 / 39987

2. **Species (common name) of animals used in the study:** Dogs

3. **Number of animals used in the study:** 78

4. **Explain the procedure producing pain and/or distress:**

These are toxicity studies for pharmaceutical drug development and the toxicities of novel compounds being tested are unknown. Animals will receive either an acute dose (1-4 times a day for 1 day) or repeat doses (1-4 times a day for up to 30 days). Dose administration routes may be orogastric, oral/pill, intravenous bolus injection, intravenous infusions, subcutaneous, intramuscular, ocular/topical, or ocular/intravitreal. Animals may experience toxic side effects from these novel compounds, both transient and prolonged, for which pain and/or distress cannot be relieved. Clinical signs suggestive of pain and distress include, but are not limited to: severe inactivity, lethargy, emesis, significant decrease in food consumption, dehydration, weight loss, hypothermia, abnormal behaviors and central nervous system changes (e.g. convulsions, aggression, paralysis, tremors, sleepiness, self-mutilation), difficulty breathing, salivation/lacrimation, obvious bleeding from one or more orifice, blood in urine/feces, diarrhea and hunched posture. Although infrequent, mortality may result due to the severity and duration of one or more of the above-mentioned effects. The attending veterinarian will be consulted on adverse reactions as appropriate. If it is determined that an animal will not recover, or if toxicity is severe, euthanasia will be performed. Examples of criteria that may be used to euthanize animals include, but are not limited to, more than 30% decrease in body weight over a 2-week period and lethargy for more than 3 days. The severity and duration of one or more of the mentioned effects, with consideration of the attending veterinarian consultation, will be used as criteria to euthanize animals.

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 these studies is to identify potential toxicities associated with new chemical entities. Depending upon the type of toxicity and its mechanism, the animal may recover or rebound. This type of data is an important finding, and the use of sedatives or pain relieving agents may confound this important data.

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):**

Agency: Food and Drug Administration
CFR: 21 CFR 312.23(a) (8) (ii) (b), 314.50 (d)