

FORM APPROVED  
OMB NO. 0579-0036

**Bayer Corporation**  
**800 Dwight Way, P.O. BOX 1986**  
**Berkeley, CA 94701-1986**

### FACILITY LOCATIONS (Sites)

**Bayer Pharmaceutical, Berkeley, CA 94701**

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. <i>(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).</i>	F.  TOTAL NO. OF ANIMALS  (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		610			610
7. Hamsters					
8. Rabbits	12	1,245	75	24	1,344
9. Non-human Primates			112		112
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

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 provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME &amp; TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED \_\_\_\_\_

93R0018

Registration No. 93-R-0018

**EXPLANATION OF A PROCEDURE PRODUCING PAIN OR DISTRESS IN RABBITS**

24 rabbits were injected with lactic acid intravenously. This caused an apparent transitory discomfort lasting from a few seconds up to two minutes. A test for pyrogens in materials used in pharmaceuticals is required by the FDA. This test must be run per the USP procedure which does not provide for anesthetics or analgesics to be used. The company completed in-house testing and validation of the Limulus Amebocyte Lysate (LAL) assay for use in lactic acid screening and replaced the rabbit pyrogenicity test for lactic acid with this *in vitro* assay after the use of these 24 rabbits. The FDA approved this test change.

