

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 14-R-0187 CUSTOMER NUMBER: 40469	FORM APPROVED OMB NO. 0579-0036
Cubist Pharmaceutical Inc 65 Hayden Ave. Lexington, MA 02421 Telephone: (781)-860-8378		

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)

(b)(2)High, (b)(7)f

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 animal 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 in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)	
4. Dogs	None ↓					
5. Cats						
6. Guinea Pigs						
7. Hamsters			443	0	244	687
8. Rabbits						
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 an 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.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
 (Chief Executive Officer or Legally Responsible Institutional Official)

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

DATE SIGNED
 11/21/08
NP

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: 14-R-0187

2. Number 687 total of animals used in this study; 244 were classified in Column E.

3. Species (common name) Hamsters of animals used in the study.

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

The hamsters are used in an animal model of *C. difficile*-associated disease or CDAD. Novel agents are being developed and tested to establish better therapeutics for treating CDAD in people. The hamster CDAD model is the accepted and most commonly used model for this disease in the literature. Control animals, and animals treated with ineffective doses of new compounds will develop CDAD and most will die overnight. The hamsters may develop diarrhea or lose weight just prior to death.

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)

One cannot reliably predict which animals will die of CDAD even when they show symptoms (e.g., diarrhea). Some recover and it is critical to know if therapy allows them to recover. Identifying new and improved therapies requires that no adjunctive treatment be given as this may influence the results. All hamsters that died on study have been counted in Category E; many died quickly with no obvious signs of pain or distress. Moribund hamsters were euthanized.

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 not applicable CFR