

**Optional Column E Explanation Form**

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.

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1. Registration Number: 41-R-0005
2. Number 370 of animals used in this study.
3. Species (common name) rabbit of animals used in this study.
4. Explain the procedure producing pain and/or distress.

This laboratory studies staphylococcal, streptococcal, and enterococcal factors that lead to production of toxic shock syndromes or endocarditis. Toxic shock syndromes by definition require hypotension/shock to be present for diagnosis, and thus, for our studies, we must allow progression to at least that point. The end point is failure of rabbits to exhibit escape behavior combined with inability to right themselves. This is particularly important to assess the protective ability of toxoid vaccines we have developed. At that time the animals are euthanized.

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 question 6 below)

There have been many published studies indicating pain relieving medications are in fact risk factors for development of toxic shock syndromes. Although the exact mechanism underlying the increased risk is unclear, there is evidence to suggest that the toxins have significant effects on the host nervous system, and thus may synergize with pain relieving medications. It is for this reason that we do not administer such medications in certain experiments.

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 \_\_\_\_\_ CFR \_\_\_\_\_

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0121

FORM APPROVED  
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)

Merial Limited  
2100 Ronson Road  
Iselin, NJ 08830

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Show)

(1) Ames Main Facility

(2) Athens Research Center

(3) Missouri Research Center

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 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. (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).	F. TOTAL NO. OF ANIMALS  (Cols. C + D + E)
4. Dogs		668	30	90	788
5. Cats		162			162
6. Guinea Pigs		256	36		292
7. Hamsters		5351		2294	7645
8. Rabbits			367		367
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Coats		1	17		18
13. Other Animals					
Raccoons		72			72
Ferrets		39		86	125

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic 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.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL.  
(Chief Executive Officer or Legally Responsible Institutional Official)  
I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE OF INSTITUTIONAL OFFICIAL

NAME AND TITLE OF INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED