November 25, 2003

Annual report of the Center for Veterinary Biologics - Laboratory (CVB-L) for the period of

1. All facilities are located at the 1800 Dayton Road location.

2. Statement of reasons for not using drugs in experiments involving pain and distress:
   
   The CVB-L's main function is the testing of veterinary biologicals for safety, efficacy, and
   purity. Drugs to alleviate pain and distress produced by the infectious disease agents are
   contraindicated as they suppress the immune system causing the disease to be more severe and
   run a longer course. Most cases are also not allowed according to the requirements found in the
   9 CFR, Chapter 113. Making sick animals comfortable and disturbing them as little as possible
   provides better treatment to these animals and quicker recovery than occurs by administering
   pain relievers. Euthanasia or curative treatments are employed as soon as allowed by the Animal
   Care and Use Committee approved animal use procedure.

3. Exceptions to adherence to the standards and regulations under the Act: None

4. Protocols involving unresolved pain or distress were as follows:

   See following attachments for Facility 42-F-008
This form is intended as an aid to completing the Coluna 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 Coluna E explanation must be written so as to be understood by a lay persons as well as scientists.

1. Registration Number: 42-F-0008

2. Number _104_ in Cat. B of __ of animals in this study.

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

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

_Clostridium chauvei_ and _C. haemolyticum_ challenge造成 animals became ill from challenge with these organisms as required by 9 CFR 113.

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)

Mandated by 9 CFR 113

6. What, if any, federal regulations require this procedure? Give the agency, the title of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

APHIS, 9 CFR 113.106 and 113.197
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: 423.F.0008

2. Number _96 (12 in Cat E) ______________ of animals in this study.

3. Species (common name) Guinea Pigs ______________ of animals used in the study.

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

Potency testing of tetanus toxoid and antitoxin - animal getting insufficient protection from the tetanus antitoxin become sick from tetanus toxin challenge.

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)

Mandated by 9 CFR 113

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):

APHIS, 9 CFR 113.134 and 113.421
This form is intended as an aid to completing the Column B 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 B explanation must be written so as to be understood by a lay person as well as scientists.

1. Registration Number: 42-2-0008

2. Number _3800 (050 in Cat. E) _______ of animals in this study.

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

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

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)

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., AFRS, 9 CFR 113.102; Animal Welfare Act, 20 U.S.C. 201, 213.103, and 113.104 which are all 20 U.S.C. 213.105 et seq.)