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Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2021

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
Column E Explanation
(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER

55-R-0127

2. Research Facility Headquarters address

8368 US 70 Bus. Hwy W
Clayton, NC 27520

3. Number of animals used in the study.

1116

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

Guinea Pig

5. Explain the procedure producing pain and distress.

Tetanus Potency- To quantitate the potency of Tetanus Immune Globulin (Human) by using neutralization methodology. Some of the animals will experience paralysis.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The testing is mandated by Product License Testing Requirements. Administration of anesthetics, analgesic or tranquilizer drugs would interfere with the outcome of the test.

7. 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 FDA

CFR 21CFR610.10

APHIS FORM 7023B
JUL 2020