

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.		OMB APPROVED 0579-0036
		Interagency Report Control No. 0183-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	