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 0579-0035

Interagency Report Control No. 0180-DOA-AN

Fiscal year:

2019-2020

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility Column E Explanation

(TYPE OR PRINT)

	. Failure to report according to the regulations can result in an order to
This information is required by law [7 U.S.C. 2143 and 9 C.F.R. 92.30]	. Panute to report accounting o
cease at	nd desist.

1. REGISTRATION NUMBER

.

2. Research Facility Headquarters address

1250 South Collegeville Road, Collegeville PA 19426

3. Number of animals used in the study.

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

One

23-R-0012

Monkey

5. Explain the procedure producing pain and distress.

One monkey was part of a toxicology study evaluating novel compounds. The monkey was given the compound intravenously and exhibited abnormal clinical signs including an elevated temperature and slight decrease in activity. The animal appeared bright, alert and moving normally the next day. Two days later the animal developed an ulcerated area at the site of the intravenous injection and continued to appear bright, alert and eating well. The area gradually scabbed over but several days later the distal tail showed abnormal clinical signs consistent with compromised circulation. The animal was then removed from study and treatment was initiated including analgesics.

6. Provide the scientific justification for not providing the appropriate and distress greater than momentary or slight.

No analgesics, anesthetics or sedatives were given because it would have confounded the study that was conducted in accordance with US Food and Drug Administration Good Laboratory Practice for Non-Clinical Laboratory Studies.

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

US Food and Drug Administration

CFR

21 CFR Part 5858

Uploaded to Animal Research Laboratory Overview (ARLO) on 05/21/2021

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OMB APPROVED 0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year:

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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 23-R-0012 2. Research Facility Headquarters address 1250 South Collegeville Road, Collegeville PA 19426 3. Number of animals used in the study. Two 4. Species (common name) of animals used in the study. Monkey

5. Explain the procedure producing pain and distress.

Two monkeys were given a novel compound for a toxicology study. One monkey developed clinical signs including elevated temperature, decreased activity and recumbency. The animal sat up and ate when staff offered supplemental food. The animal's condition improved (e.g. decreased temperature, increased activity) the next day and during subsequent days. A second monkey exhibited lethargy and decreased appetite but accepted supplemental food. The animal was reported to be bright, alert and responsive the next day.

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.

No analgesics, anesthetics or sedatives were given because it would have confounded the study that was conducted in accordance with US Food and Drug Administration Good Laboratory Practice for Non-Clinical Laboratory Studies.

7. What, if any, Federal regulations require this procedure? Cite the ag	jency, the Code of
Federal Regulations (CFR) title number, and the specific section number	
113. 102):	

Agency

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US Food and Drug Administration

CFR

21 CFR Part 5858

Uploaded to Animal Research Laboratory Overview (ARLO) on 05/21/2021