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)

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.

One

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

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 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 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

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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 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