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OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2017

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

MERCK SHARP & DOHME CORP
126 E LINCOLN AVE, RY 33-508

RAHWAY, NJ 07065

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

[redacted]

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	72	657	116	0	773
5. Cats	0	0	0	0	0
6. Guinea Pigs	34	443	371	4	818
7. Hamsters	0	0	0	0	0
8. Rabbits	71	849	178	3	1030
9. Non-human Primates	48	1148	232	4	1384
10. Sheep	0	0	0	0	0
11. Pigs	0	3	11	0	14
12. Other Farm Animals					
13. Other Animals	29	0	920	0	920

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
07-FEB-2018

APHIS FORM 7023
JUL 2013

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2017

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

MERCK SHARP & DOHME CORP
126 E LINCOLN AVE, RY 33-508

RAHWAY, NJ 07065

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
COTTON RATS	29	0	920	0	920

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
07-FEB-2018

APHIS FORM 7023A
AUG 2013

B. Summary of exceptions to the regulations and standards October 1, 2016 - September 30, 2017

Exceptions to the standard 2-week cage sanitation program

Twenty-four non-human primates were considered as exceptions to the standard 2-week complete cage sanitation program for the conduct of telemetry data collection studies. There was one occurrence with seventeen non-human primates and two occurrences with seven non-human primates where the sanitation was extended between 15 to 20 days. However, the standard daily cleaning of the cages was maintained during this period. The IACUC approved these exceptions based on scientific justification.

A room housing twenty-three dogs incurred a deviation to the standard 2-week complete kennel sanitation program; the sanitation was extended until 16 days. However, the standard daily cleaning of the kennels was maintained during this period.

A. Column E Explanation (all studies listed below were approved by the IACUC at their respective site):

Four guinea pigs developed surgical complications following an intravascular implantation of a telemetry device and died before euthanasia could be accomplished.

Three rabbits developed acute terminal complications while on toxicology studies and died before euthanasia could be accomplished.

One nonhuman primate developed complications while on a toxicology study and died before euthanasia could be accomplished.

Three nonhuman primates were euthanized after developing weight loss while on a toxicity study.

The activities and procedures of conduct for the above-referenced studies were reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). Animals used on product release testing and toxicology studies were required by federal regulations for submission regarding safety and toxicity testing. The regulations that require these procedures include 21 CFR 58 (FDA) and 21 CFR 610.11 (FDA).

29 NOV 2017