



Inspection Report

Boehringer Ingelheim Pharmaceuticals Inc
900 Ridgebury Road, Box 368
Ridgefield, CT 06877

Customer ID: 55

Certificate: 16-R-0029

Site: 001

BOEHRINGER INGELHEIM RESRCH. & DEVELOP.

Type: ROUTINE INSPECTION

Date: 17-APR-2017

There were no non-compliant items identified during the inspection.

NOTE - Inspection conducted 4/17/17 and 4/18/17. Exit briefing held on-site 4/18/17 with facility representatives.

END OF REPORT

Prepared By:

GLADUE PAULA, V M D USDA, APHIS, Animal Care

Date:
18-APR-2017

Title: VETERINARY MEDICAL OFFICER 1054

Received By:

(b) (6), (b) (7)(C)

Title: INSTITUTIONAL OFFICIAL BOEHRINGER INGELHEIM
19-01618_000024

Date:
18-APR-2017



| Cust No | Cert No | Site | Site Name | Inspection |
|---------|-----------|------|---|------------|
| 55 | 16-R-0029 | 001 | BOEHRINGER INGELHEIM PHARMACEUTICALS INC | 17-APR-17 |

| Count | Species |
|---------------|---|
| 000058 | DOG ADULT |
| 000066 | CRAB-EATING MACAQUE / LONG-TAILED MACAQUE / CYNOMOLGUS MONKEY |
| 000124 | Total |



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900 Ridgebury Road, Box 368
Ridgefield, CT 06877

Customer ID: 55

Certificate: 16-R-0029

Site: 001

BOEHRINGER INGELHEIM RESRCH. & DEVELOP.

Type: ROUTINE INSPECTION

Date: 12-JUN-2018

There were no non-compliant items identified during the inspection.

NOTE - Exit briefing held on-site 6/12/18 with facility representatives.

END OF REPORT

Prepared By:

GLADUE PAULA, V M D USDA, APHIS, Animal Care

Date:

12-JUN-2018

Title: VETERINARY MEDICAL OFFICER 1054

Received By:

(b) (6), (b) (7)(C)

Title: INSTITUTIONAL OFFICIAL BOEHRINGER INGELHEIM
19-01618_000026

Date:

12-JUN-2018



Species Inspected

| Cust No | Cert No | Site | Site Name | Inspection |
|---------|-----------|------|--|------------|
| 55 | 16-R-0029 | 001 | BOEHRINGER INGELHEIM RESRCH. & DEVELOP. | 12-JUN-18 |

| Count | Scientific Name | Common Name |
|---------------|-------------------------------|---|
| 000021 | <i>Canis lupus familiaris</i> | DOG ADULT |
| 000063 | <i>Macaca fascicularis</i> | CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY |
| 000084 | Total | |

21 NOV 2017

Facility Registration Number 16-R-0029

Three NHPs assigned to Column E of this report were used in non-clinical laboratory studies to evaluate the safety of test compounds in accordance to Food and Drug Administration requirements under Good Laboratory regulations 21 CFR 58. The animals were used on studies to determine the potential target organs of toxicity and no effect levels of test articles that were administered. During the course of the studies, these animals exhibited one or more clinical signs on one or more days that included lethargy, mild gastrointestinal discomfort, and irregular respiration. These NHPs were not given other drugs, such as analgesics or sedatives that might induce their own inherent toxicities, drug-drug interactions, or otherwise confound interpretation of toxicological effects of the test article. Animals were, however, provided fluids, nutritional supplements and other palliative care that mitigated their clinical signs. Animals were also placed on dosing holidays to help stabilize their condition. At the earliest indication of clinical signs meeting pre-determined humane endpoints, these animals were removed from study and euthanized.

21 NOV 2017

| | | |
|-----------------|----------------------------|--------------------|
| To: | 2017 AR Review Coordinator | Facility Contact: |
| Facility Name: | | Facility Reg. No.: |
| Facility Fax: | | No. of Pages: |
| Facility Phone: | | Date: |

NO ANNUAL REPORT ATTACHMENTS SUBMITTED TO AC FOR 2017

☐ We did not submit AR Attachments to AC for 2017.

NO OBJECTIONS RESPONSE

☒ We have no objections to the release of our AR Attachments as received and do not intend to seek judicial review to bar release of these documents.

REDACTIONS PURSUANT TO EXEMPTION 4 REQUESTED

☐ We object to the release of our AR Attachments as received and ask that you consider the enclosed justification statement and suggested redactions.

COMMENTS

Signature

(b) (6), (b) (7)(C)

Date

15 Nov 2017

(b) (6), (b) (7)(C)

Print Name (if different from above)