

Four dogs 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 gastrointestinal discomfort, weight loss, and subtle neurological signs. The dogs 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

**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**

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

Signature

Date

15 Nov 2017

WANDA L. WEST, DVM, PhD, DACLAM

Print Name (if different from above)

## **Facility Registration Number 16-R-0029**

The one NHP assigned to Column E of this report was used in a non-clinical laboratory study to evaluate test compound safety in accordance to Food and Drug Administration requirements under Good Laboratory Regulations 21 CFR 58. During the course of study, the NHP exhibited clinical signs including lethargy. 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, were not administered. When the NHP's clinical presentation became consistent with the IACUC-approved humane endpoints, the animal was euthanized.

28 NOV 2018



## Inspection Report

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Boehringer Ingelheim Pharmaceuticals Inc

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

Customer ID: 55

Certificate: 16-R-0029

Site: 001

BOEHRINGER INGELHEIM RESRCH. & DEVELOP.

Type: ROUTINE INSPECTION

Date: 17-APR-2017

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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\*

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**Prepared By:**

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

**Title:** VETERINARY MEDICAL OFFICER 1054

**Date:**  
18-APR-2017

**Received By:**

JAMES G. BAXTER, PHARM.D., PH.D

**Title:** INSTITUTIONAL OFFICIAL BOEHRINGER INGELHEIM

**Date:**  
18-APR-2017

Obtained by Rise for Animals. Uploaded 07/10/2020



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
<b>000124</b>	<b>Total</b>



## Inspection Report

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Boehringer Ingelheim Pharmaceuticals Inc

Customer ID: 55

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

Certificate: 16-R-0029

Site: 001

BOEHRINGER INGELHEIM RESRCH. & DEVELOP.

Type: ROUTINE INSPECTION

Date: 12-JUN-2018

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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\*

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**Prepared By:**

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

**Date:**  
12-JUN-2018

**Title:** VETERINARY MEDICAL OFFICER 1054

**Received By:**

JAMES G. BAXTER, PHARM.D., PH.D.

**Obtained by Rise for Animals. Uploaded 07/10/2020**

**Title:** INSTITUTIONAL OFFICIAL BOEHRINGER INGELHEIM

**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
<b>000084</b>	<b>Total</b>	



## Inspection Report

Boehringer Ingelheim Pharmaceuticals Inc

Customer ID: 55

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

Certificate: 16-R-0029

Site: 001

BOEHRINGER INGELHEIM RESRCH. & DEVELOP.

Type: FOCUSED INSPECTION

Date: 24-APR-2019

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

NOTE - Exit briefing held 4/24/19 on-site with facility representatives.

\*END OF REPORT\*

Prepared By:

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

Date:  
24-APR-2019

Title: VETERINARY MEDICAL OFFICER 1054

Received By:

Obtained by Rise for Animals. Uploaded 07/10/2020

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

Title:

Date:  
24-APR-2019



## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
55	16-R-0029	001	BOEHRINGER INGELHEIM RESRCH. & DEVELOP.	24-APR-19

Count	Scientific Name	Common Name
000045	<i>Canis lupus familiaris</i>	DOG ADULT
000053	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
<b>000098</b>	<b>Total</b>	

## Research Facility Protocol Selection Worksheet <sup>\*</sup>

**Legal Name:** Boehringer Ingelheim

**Customer Number:** 55

**Certificate Number:** 16-R-0029

**Site Number:** 001

**Inspection Date:** 4/24/19

**Inspection Type:** Routine ☐ Focused ☒ (list areas inspected) Animals and animal housing; IACUC minutes; Reports to IO

**Inspector:** PSGladue, VMD

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	0
2. Column E protocols ( select all)	0
3. Protocols with IACUC-approved exemptions/exceptions (select all)	0
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining:  b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	0
<b>Total Protocols Selected and Reviewed</b>	0

**\*Note:** Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

**From:** (b) (6), (b) (7)(C)  
**To:** Gladue, Paula S - APHIS  
**Cc:** (b) (6), (b) (7)(C)  
**Subject:** RE: \*\*\*Action required - USDA inspection report BIPI 4/24/19 focused  
**Date:** Thursday, April 25, 2019 11:40:19 AM

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Dear Dr. Gladue,

thank you for the USDA inspection report. I am very pleased, that the inspection went well.  
I herewith confirm that I have received the inspection and inventory reports today in PDF format.  
I am sorry, that I could not make it in time for the exit briefing meeting yesterday. I would have liked to introduce myself to you and meet you in person.  
Please let me know, if there is anything else I need to do.  
Hope to meet you next time.

Regards

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

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**From:** Gladue, Paula S - APHIS <paula.s.gladue@usda.gov>  
**Sent:** Thursday, April 25, 2019 9:47 AM  
**To:** (b) (6), (b) (7)(C)  
**Cc:** (b) (6), (b) (7)(C)  
**Subject:** \*\*\*Action required - USDA inspection report BIPI 4/24/19 focused  
**Importance:** High

Good morning (b) (6),  
(b) (7)

Here are the inspection and inventory reports from the inspection conducted Wednesday 4/24/19 plus the Research Protocol Selection form. Please note that if you are viewing this e-mail on an iPhone that the RPS form may appear blank but is filled out when viewing it on a computer. We are required to prepare one of these forms for every research facility inspection even when no protocols were reviewed.

I have sent the inspection report in a PDF format. \*\*\***Please acknowledge within 5 days that you successfully received the inspection report via a return e-mail to me.**\*\*\* The return e-mail takes the place of a "received by" signature on the report.

If you are having any difficulty sending an e-mail response, please let me know by calling me at 860-423-6431 and I can send the report to you by a different method.

Thank you and I hope you have a nice weekend.

Paula S. Gladue, V.M.D.

USDA/APHIS/Animal Care  
P.O. Box 117; Willimantic; CT 06226  
Office (860) 423-6431

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MAR 01 2017

Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 of the Animal Welfare Act, shall register with the USDA (7 USC 2136). This application provides information for such registration.		OMB No. 0579-0036 FORM APPROVED	
U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE <b>APPLICATION FOR REGISTRATION</b> (TYPE OR PRINT)  <b>REGISTRATION UPDATE</b>		<b>USDA USE ONLY</b> Applicant should send completed form to this address. USDA APHIS ANIMAL CARE EASTERN 920 Main Campus Drive Suite 200 Raleigh, NC 27606-5210 (919) 855-7100	
		<b>CERTIFICATE NO./CUST NO:</b> 16-R-0029  55	<b>RENEWAL DATE</b> 27-Mar-2017  <i>Vme.</i>
1. REGISTRANT (Name and permanent mailing address, including Zip Code) Boehringer Ingelheim Pharmaceuticals Inc (b) (6), (b) (7)(C)		2. LOCATION (S) OF BUSINESS, EXHIBITION SITE(S), OR RESEARCH FACILITIES (Use additional sheets if necessary) (b) (6), (b) (7)(C)	
COUNTY: (b) (6), (b) (7)(C)		4. (B) ACTIVE USDA CERTIFICATE NUMBER(S) IN WHICH YOU HAVE AN INTEREST:	
3. (A) PREVIOUS USDA REGISTRATION NUMBER (IF ANY)			
5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT RESEARCH, TESTS, OR EXPERIMENTS  <input type="checkbox"/> Yes <input type="checkbox"/> No		6. TYPE OF REGISTRATION: <input type="checkbox"/> Class E – Exhibitor <input type="checkbox"/> Class H – Intermediate Handler <input type="checkbox"/> Class R – Research Facility <input type="checkbox"/> Class T – Carrier	
7. FEDERAL FUND TYPES: <input type="checkbox"/> Award <input type="checkbox"/> Contract <input type="checkbox"/> Grant <input type="checkbox"/> Loan		8. TYPE OF ORGANIZATION: <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation <input type="checkbox"/> Individual <input type="checkbox"/> Other (Specify) _____	
9. IF INDIVIDUAL IDENTIFY EACH OWNER, IF PARTNERSHIP IDENTIFY EACH PARTNER OR OFFICER, IF CORPORATION, IDENTIFY PRINCIPAL OFFICERS FOR RESEARCH FACILITIES INCLUDE THE INSTITUTIONAL OFFICIAL (Use separate sheet if needed)			
A. NAME	B. TITLE	C. ADDRESS (full address, including ZIP Code)	
✓ Paul Fonteyne	Chief Executive Officer	(b) (6), (b) (7)(C)	
✓ Jean-Michel Boers	President		
✓ Desiree Ralls-Morrison	Senior VP and General Counsel and Secretary		
✓ Christian Orth	Senior VP and Chief Financial Officer		
✓ Paula Wittmayer	Assistant Secretary		
✓ Frank A. Pomer	Assistant Secretary		
✓ James G. Baxter, Ph.D.	Senior VP, Development Institutional Official		
CERTIFICATION			
I hereby register as a Research Facility, Exhibitor, Carrier, or Intermediate Handler under the Animal Welfare Act, 7 U.S.C. 2131 et seq. and I certify that the information provided herein is true and correct to the best of my knowledge. I hereby acknowledge receipt of and agree to comply with all the regulations and standards contained in 9 CFR, Subpart A, parts 1, 2 and 3. I certify that all listed persons are 18 years of age or older.			
10. SIGNATURE (b) (6), (b) (7)(C)		11. NAME AND TITLE (Type or Print) James, G. Baxter, Ph.D.	12. DATE SIGNED 27-Feb-2017

APHIS FORM 7011  
(FEB 2009)

ACKNOWLEDGEMENT OF RECEIPT OF REGULATIONS AND STANDARDS



United States  
Department of  
Agriculture

Marketing and  
Regulatory  
Programs

Animal and  
Plant Health  
Inspection  
Service

Animal Care

EXPIRATION DATE: MARCH 27, 2020

This is to certify that

BOEHRINGER INGELHEIM PHARMACEUTICALS INC

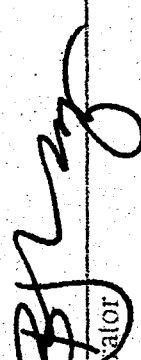
is a registered  
under the  
CLASS R RESEARCH FACILITY

## Animal Welfare Act

(7 U.S.C. 2131 et seq.)

Certificate No. 16-R-0029

Customer No. 55

  
Deputy Administrator



Elizabeth Goldentyer, DVM  
United States Department of Agriculture  
Regional Director - Animal Care  
Eastern Region  
920 Main Campus Drive  
Suite 200  
Raleigh, NC 27606

Boehringer Ingelheim  
Pharmaceuticals Inc.

16-R-0029  
#55

November 27, 2017

#### Recent Reorganization

Dear Dr. Goldentyer,

I wanted to make you aware that, as of November 8, 2017, I have assumed the duties of interim Attending Veterinarian/Director at Boehringer Ingelheim Pharmaceuticals, Inc.

Should you have any questions regarding this matter, please do not hesitate to contact me.

Sincerely yours,

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

Wanda L. West, DVM, PhD, DACLAM  
Director/Attending Veterinarian, Animal Resources  
Global Animal Care and Welfare Officer

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E-Mail wanda.west@boehringer-  
ingelheim.com  
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Ridgefield, CT 06877-0368

30 NOV 2017