



## Inspection Report

PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: 339

Certificate: 21-R-0088

Site: 001

PFIZER CENTRAL RESEARCH

CENTRAL RESEARCH DIVISION

235 EAST 42ND STREET

Type: ROUTINE INSPECTION

Date: Mar-16-2010

NEW YORK NEW YORK, NY 10017

### 2.31 (d) (1) (ii)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (ii) - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources.....used to determine that alternatives were not available."

1. Review of Protocol #15443 and the amendment approved on 3/15/10:

a. The written narrative of the methods and sources used to determine that alternatives were not available to the potentially painful or distressful procedures described in the proposal for animal use does not include the procedure of telemetry device implantation that is described in the amendment.

In order to approve proposed animal use activities or proposed significant changes to ongoing activities, the IACUC should determine that the proposed activities/changes meet the requirements as described in Section 2.31 (d) (1).

The Registrant corrected this item during the inspection by the IACUC contacting the investigator to request that modifications to the animal use proposal be submitted to the IACUC for review.

NOTE - This was a complete facility inspection conducted from 3/16/10 through 3/17/10 with the exit on 3/18/10.

**Prepared By:**

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

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1054

Mar-18-2010

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Mar-18-2010



## Inspection Report

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PFIZER GLOBAL RESEARCH &

Customer ID: **339**

CENTRAL RESEARCH DIVISION

Certificate: **21-R-0088**

235 EAST 42ND STREET

Site: 001

PFIZER CENTRAL RESEARCH

NEW YORK NEW YORK, NY 10017

Type: ROUTINE INSPECTION

Date: Apr-07-2009

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There were no non-compliant items identified during the inspection. Registrant was in compliance with AWA Regulations and Standards at the time of the inspection.

NOTE - This was a full facility inspection conducted on 4/7/09 and 4/8/09 with the exit interview on 4/8/09.

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**Prepared By:**

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

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1054

Apr-08-2009

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Apr-08-2009



## Inspection Report

PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 001

PFIZER CENTRAL RESEARCH

CENTRAL RESEARCH DIVISION

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: Jan-15-2008

There were no non-compliant items identified during the inspection. Facility was in compliance with AWA Regulations and Standards at the time of the inspection.

NOTE - This was a full facility inspection conducted on 1/15/08 and 1/16/08, with the exit interview held on 1/16/08.

**Prepared By:**

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

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1054

Jan-16-2008

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Jan-16-2008



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 004

CENTRAL RESEARCH DIVISION

235 EAST 42ND STREET

NEW YORK NEW YORK, NY 10017

PFIZER GLOBAL RESEARCH & DEVELOPMENT-LA JOLLA LABS

Type: ROUTINE INSPECTION

Date: Aug-06-2009

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No non-compliant items identified this inspection.

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**Prepared By:**

MANUEL A ADVIENTO, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 5001

Aug-06-2009

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Aug-06-2009



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 004

PFIZER GLOBAL RESEARCH & DEVELOPMENT-LA JOLLA LABS

CENTRAL RESEARCH DIVISION

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: Jul-15-2008

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No non-compliant items identified this inspection.

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**Prepared By:**

MANUEL A ADVIENTO, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 5001

Jul-15-2008

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Jul-15-2008



## Inspection Report

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PFIZER GLOBAL RESEARCH &

Customer ID: **339**

CENTRAL RESEARCH DIVISION

Certificate: **21-R-0088**

235 EAST 42ND STREET

Site: 004

PFIZER GLOBAL RESEARCH &

NEW YORK NEW YORK, NY 10017

Type: ROUTINE INSPECTION

Date: Oct-10-2007

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No non-compliant items identified this inspection.

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**Prepared By:**

MANUEL A ADVIENTO, V.M.O. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 5001

Oct-10-2007

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Oct-10-2007



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 005

PFIZER GLOBAL RESEARCH AND DEVELOPMENT

CENTRAL RESEARCH DIVISION

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: Sep-22-2008

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This inspection was conducted at both locations by Dr. Jami Niemann, VMO and facility staff.

NO NON-COMPLIANT ITEMS IDENTIFIED AT THIS INSPECTION.

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**Prepared By:**

JAMILON A NIEMANN, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 4054

Sep-22-2008

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Sep-22-2008



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 005

PFIZER GLOBAL RESEARCH AND DEVELOPMENT

CENTRAL RESEARCH DIVISION

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: Sep-17-2007

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This inspection was conducted at both facilities housing covered animals by Dr. Jami Niemann, VMO, and staff.

NO NON-COMPLIANT ITEMS IDENTIFIED AT THIS INSPECTION.

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**Prepared By:**

JAMILON A NIEMANN, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** SUPERVISORY ANIMAL CARE Inspector 4054

Sep-17-2007

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Sep-17-2007





## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 007

CENTRAL RESEARCH DIVISION

VETERINARY MEDICINE RESEARCH AND DEVELOPMENT

235 EAST 42ND STREET

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: May-18-2009

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No non-compliant items identified this inspection.  
Inspection and exit interview conducted with Kurt Hammel and various officials at Pfizer.

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**Prepared By:**

KURT HAMMEL, D V M                      USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1023

May-18-2009

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

May-18-2009



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: 339

Certificate: 21-R-0088

Site: 007

VETERINARY MEDICINE RESEARCH AND DEVELOPMENT

CENTRAL RESEARCH DIVISION

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: Aug-05-2008

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No non-compliant items identified this inspection.

Inspection conducted with Kurt Hammel and clinical veterinarians, quality assurance personnel and responsible personnel from the areas inspected.

Exit interview conducted with Kurt Hammel and Pfizer senior management, clinical veterinarians, quality assurance personnel and responsible personnel from the areas inspected.

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**Prepared By:**

KURT HAMMEL, D V M                      USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1023

Aug-05-2008

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Aug-05-2008



## Inspection Report

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PFIZER GLOBAL RESEARCH &

Customer ID: **339**

CENTRAL RESEARCH DIVISION

Certificate: **21-R-0088**

235 EAST 42ND STREET

Site: 007

VETERINARY MEDICINE RESEARCH

NEW YORK NEW YORK, NY 10017

Type: ROUTINE INSPECTION

Date: Aug-22-2007

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No non-compliant items identified this inspection.

Inspection conducted with Kurt Hammel and clinical veterinarians, quality assurance personnel, and responsible personnel from the areas inspected.

Exit interview conducted with Kurt Hammel and Pfizer senior management, clinical veterinarians, quality assurance personnel and personnel responsible for the areas inspected.

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**Prepared By:**

KURT HAMMEL, D V M                      USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1023

Aug-22-2007

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Aug-22-2007



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 011

PFIZER INC

CENTRAL RESEARCH DIVISION

235 EAST 42ND STREET

Type: ROUTINE INSPECTION

Date: Sep-30-2009

NEW YORK NEW YORK, NY 10017

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There were no items documented.

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**Prepared By:**

RUTH BAKKER, D.V.M.      USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 4029

Oct-15-2009

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Oct-15-2009



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 011

PFIZER INC

CENTRAL RESEARCH DIVISION

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: Sep-30-2008

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There were no items documented at the time of this site visit.

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**Prepared By:**

RUTH BAKKER, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 4029

Sep-30-2008

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Sep-30-2008



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 014

CENTRAL RESEARCH DIVISION

235 EAST 42ND STREET

NEW YORK NEW YORK, NY 10017

PFIZER GLOBAL RESEARCH & DEVELOPMENT

Type: ROUTINE INSPECTION

Date: Aug-27-2009

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This inspection was conducted by Drs. Jami Niemann and Mike Tygart (VMO) and facility staff.

NO NON-COMPLIANT ITEMS IDENTIFIED AT THIS INSPECTION.

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**Prepared By:**

JAMILON A NIEMANN, D.V.M. USDA, APHIS, Animal Care

**Title:** VETERINARY MEDICAL OFFICER Inspector 4054

**Date:**

Aug-27-2009

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

Aug-27-2009

**Title:**



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 018

PFIZER GLOBAL RESEARCH & DEVELOPMENT

CENTRAL RESEARCH DIVISION

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: Apr-28-2010

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No regulated animals present at time of site visit. No regulated activities.

Site decommissioned.

Note: An exit briefing was conducted with the research facility representative.

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**Prepared By:**

JOEL RUBIN, V M D                      USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1059

Apr-28-2010

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Apr-28-2010



## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 019

PFIZER GLOBAL RESEARCH & DEVELOPMENT

CENTRAL RESEARCH DIVISION

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: May-19-2010

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No noncompliances noted at the time of inspection.

Exit interview conducted on May 19, 2010 with facility personnel.

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**Prepared By:**

TONYA HADJIS, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1081

May-20-2010

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

May-20-2010





## Inspection Report

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PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 020

CENTRAL RESEARCH DIVISION

235 EAST 42ND STREET

NEW YORK NEW YORK, NY 10017

PFIZER GLOBAL RESEARCH & DEVELOPMENT

Type: ROUTINE INSPECTION

Date: Mar-18-2010

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Inspection shows all standards in compliance 3/10

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**Prepared By:**

JOHN LOPINTO, D V M                      USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1008

Mar-18-2010

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Mar-18-2010



## Inspection Report

PFIZER GLOBAL RESEARCH & DEVELOPMENT

Customer ID: **339**

Certificate: **21-R-0088**

Site: 022

CENTRAL RESEARCH DIVISION

PFIZER GLOBAL RESEARCH & DEVELOPMENT

235 EAST 42ND STREET

Type: ROUTINE INSPECTION

NEW YORK NEW YORK, NY 10017

Date: Feb-24-2010

### 2.33 (b) (2)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Each research facility shall establish and maintain programs of adequate veterinary care that include:

(2) The use of appropriate methods to prevent, control, disease.

\*\*\* The top of a bottle of Betadine solution in the prep area of the large animal suite had not been adequately cleaned. Betadine residue was noted around the opening of the bottle. Thus, the use of the solution would not be consistent with aseptic technique.

This noncompliance was corrected immediately.

Prepared By:

STEVEN NUSBAUM, D V M      USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1068

Feb-24-2010

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Feb-24-2010