



Inspection Report

JOHNSON & JOHNSON PHARMACEUTICAL

Customer ID: **33183**

P O BOX 300 ROUTE 202 SOUTH

Certificate: **22-R-0138**

Site: 001

JOHNSON & JOHNSON PHARM R&D

RARITAN, NJ 08869

Type: ROUTINE INSPECTION

Date: Nov-25-2008

NO NON-COMPLIANT ITEMS IDENTIFIED DURING THIS INSPECTION.

Prepared By:

NADIRA R WILLIAMS, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1060

Nov-25-2008

Received By:

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

Date:

Title:

Nov-25-2008



Inspection Report

JOHNSON & JOHNSON PHARMACEUTICAL

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Site: 001

JOHNSON & JOHNSON PHARM R&D

RARITAN, NJ 08869

Type: ROUTINE INSPECTION

Date: Oct-15-2007

NO NON-COMPLIANT ITEMS IDENTIFIED DURING THIS INSPECTION.

End of report.

Prepared By:

NADIRA R WILLIAMS, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1060

Oct-15-2007

Received By:

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

Date:

Title:

Oct-15-2007



Inspection Report

JOHNSON & JOHNSON PHARMACEUTICAL R&D LLC

Customer ID: **33183**

Certificate: **22-R-0138**

Site: 002

P O BOX 300 ROUTE 202 SOUTH

JOHNSON & JOHNSON PHARM R&D

Type: ROUTINE INSPECTION

Date: Oct-05-2009

RARITAN, NJ 08869

No non-compliances identified this inspection.

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Oct-05-2009

Received By:

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

Date:

Title:

Oct-05-2009



Inspection Report

JOHNSON & JOHNSON PHARMACEUTICAL

Customer ID: **33183**

P O BOX 300 ROUTE 202 SOUTH

Certificate: **22-R-0138**

Site: 002

JOHNSON & JOHNSON PHARM R&D

RARITAN, NJ 08869

Type: ROUTINE INSPECTION

Date: Oct-01-2008

No non-compliances identified this inspection.

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Oct-01-2008

Received By:

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

Date:

Title:

Oct-01-2008



Inspection Report

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Customer ID: **33183**

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Site: 002

JOHNSON & JOHNSON PHARM R&D

RARITAN, NJ 08869

Type: ROUTINE INSPECTION

Date: Oct-11-2007

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(e)(2) IACUC: A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

Animal activity proposal 1850 does not provide a rationale for the appropriateness of the numbers of guinea pigs and hamsters to be used in experiments involving the administration of investigational compounds. The rationale for number of animals needs to be included in the proposal to insure a minimum number of animals is used. Correct by December 1, 2007.

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Oct-11-2007

Received By:

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

Date:

Title:

Oct-11-2007



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RARITAN, NJ 08869

Type: ROUTINE INSPECTION

Date: Apr-04-2007

2.31 (e)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(e) IACUC: A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

- (2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;
- (3) A complete description of the proposed use of the animals;
- (4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals.

Animal activity proposal 1571 does not provide an accurate description of the activity involving animals. The group size has been increased without amending the proposal and including a rationale for the appropriateness of the numbers of animals to be used. The proposal does not describe fasting the animals which was observed during this inspection. The anesthesia for blood collection described in section 8 on page 26 is not used according to the investigator. The Investigator must provide complete and accurate information in the animal proposal for the IACUC to appropriately review to insure animal pain and distress is minimized.

Animal activity proposal 2016 described the use of anesthesia for an initial procedure and for euthanasia. The investigator explained why anesthetics, sedatives and analgesics could not be used for pain/distress relief during the short experiment. However, according to the investigators the animals are given short acting anesthetics during the course of the short experiment to obtain measurements but the animals do not remain unconscious for the entire experiment. If animals can receive anesthetics for measurements then the explanation given for not relieving pain/distress is no longer valid. The proposal needs to include appropriate pain relief for the animals to minimize pain and distress.

Animal activity proposal INF-02-04-04-1508 describes using 6-10 animals per group, but the rationale for the appropriateness of the numbers of animals used is for 5 animals per group. The rationale for number of animals needs to correspond to the number of animals requested in the proposal to insure a minimum number of animals is used.

Correct by June 1, 2007.

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Apr-04-2007

Received By:

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

Date:

Title:

Apr-04-2007



Inspection Report

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Date:

Apr-04-2007

Received By:

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

Date:

Apr-04-2007

Title:



Inspection Report

JOHNSON & JOHNSON PHARMACEUTICAL R&D LLC

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Certificate: **22-R-0138**

Site: 003

P O BOX 300 ROUTE 202 SOUTH

JOHNSON & JOHNSON PHARM R&D

Type: ROUTINE INSPECTION

Date: Nov-24-2009

RARITAN, NJ 08869

No non-compliant items identified this inspection.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5001

Nov-24-2009

Received By:

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

Date:

Title:

Nov-24-2009



Inspection Report

JOHNSON & JOHNSON PHARMACEUTICAL

Customer ID: **33183**

P O BOX 300 ROUTE 202 SOUTH

Certificate: **22-R-0138**

Site: 003

JOHNSON & JOHNSON PHARM R&D

RARITAN, NJ 08869

Type: ROUTINE INSPECTION

Date: Apr-07-2009

No non-compliant items identified this inspection.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5001

Apr-07-2009

Received By:

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

Date:

Title:

Apr-07-2009



Inspection Report

JOHNSON & JOHNSON PHARMACEUTICAL R&D LLC

Customer ID: **33183**

Certificate: **22-R-0138**

Site: 003

JOHNSON & JOHNSON PHARM R&D

P O BOX 300 ROUTE 202 SOUTH

Type: ROUTINE INSPECTION

RARITAN, NJ 08869

Date: Jul-15-2008

No non-compliant items identified this inspection.

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



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Site: 003

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Type: ATTEMPTED INSPECTION

Date: May-06-2008

2.38 (b)
MISCELLANEOUS.

A responsible adult shall be made available to accompany APHIS officials during the inspection process.

- Responsible individuals can not be contacted and available to allow access and accompany routine inspection between 1025-1040 on May 6, 2008.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5001

May-06-2008

Received By:

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

Date:

Title:

May-07-2008



Inspection Report

JOHNSON & JOHNSON PHARMACEUTICAL

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Certificate: **22-R-0138**

Site: 003

JOHNSON & JOHNSON PHARM R&D

RARITAN, NJ 08869

Type: ROUTINE INSPECTION

Date: Oct-10-2007

No non-compliant items identified this inspection.

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



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Certificate: **22-R-0138**

Site: 003

JOHNSON & JOHNSON PHARM R&D

RARITAN, NJ 08869

Type: ROUTINE INSPECTION

Date: Feb-20-2007

No non-compliant items identified this inspection.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5001

Feb-20-2007

Received By:

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

Date:

Title:

Feb-20-2007