



## Inspection Report

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MOMENTA PHARMACEUTICALS

Customer ID: **31312**

Certificate: **14-R-0173**

Site: 001

675 WEST KENDALL STREET

MOMENTA PHARMACEUTICALS

Type: ROUTINE INSPECTION

Date: Oct-22-2009

CAMBRIDGE, MA 02030

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Facility is in compliance with AWA Regulations and Standards at the time of inspection.

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**Prepared By:**

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

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1081

Oct-22-2009

**Received By:**

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

**Date:**

**Title:**

Oct-22-2009



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Customer ID: **31312**

675 WEST KENDALL STREET

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Site: 001

MOMENTA PHARMACEUTICALS

CAMBRIDGE, MA 02030

Type: ROUTINE INSPECTION

Date: Mar-31-2009

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Facility is in compliance with AWA Regulations and Standards at the time of inspection.

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**Prepared By:**

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

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1081

Mar-31-2009

**Received By:**

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

**Date:**

**Title:**

Mar-31-2009



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675 WEST KENDALL STREET

Type: ROUTINE INSPECTION

CAMBRIDGE, MA 02030

Date: Aug-11-2008

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No non compliances identified during this inspection.

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**Prepared By:**

MICHAEL J SMITH, D.V.M.      USDA, APHIS, Animal Care

**Date:**

**Title:**      SUPERVISORY ANIMAL CARE      Inspector 5019

Aug-11-2008

**Received By:**

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

**Date:**

**Title:**

Aug-11-2008



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MOMENTA PHARMACEUTICALS

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675 WEST KENDALL STREET

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Site: 001

MOMENTA PHARMACEUTICALS

CAMBRIDGE, MA 02030

Type: ROUTINE INSPECTION

Date: Feb-06-2007

### 2.31 (e) (3)

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

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

(3) A complete description of the proposed use of the animals.

\*\*\*\*Protocol #05-2005: The research activities that were conducted on 1/8/06 on 12 rabbits did not follow the activities described in the approved IACUC protocol. The protocol states that rabbits will be anesthetized and then have blood collected for up to 12 hrs post drug administration. The protocol states that animals will then be allowed to rest for a week and the procedure will be repeated for a maximum of 4 times. 12 rabbits (# 1C-12C) were anesthetized once on 1/8/06, had blood collected post drug administration and were euthanized the following day, 1/9/06. A complete description of all activities involving animals must be included in protocols to ensure appropriate handling. IACUC must address this issue. Correct by 3/14/07.

### 2.31 (e) (5)

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

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

(5) A description of any euthanasia method to be used.

\*\*\*\*Protocol 05-2005: In the documents available for review, on 1/9/06, 12 rabbits were euthanized using methods other than those described in the IACUC approved protocol. The protocol states rabbits will be euthanized using acepromazine sedation followed by IV pentobarbital. The records for rabbits (1C-12C) euthanized on 1/9/06 do not document the use of acepromazine sedation prior to euthanasia with pentobarbital. A complete description of euthanasia must be included in protocols to assure humane methods of euthanasia. IACUC must address this issue.

#### Prepared By:

REBECCA B CHAFEL, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1071

Feb-06-2007

#### Received By:

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

Date:

Title:

Feb-06-2007



## Inspection Report

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Correct by 3/14/07.

**2.31** (c) (7)

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

2.31(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

\*\*\*\*Protocol 01-2006 amendment: 7 rabbits (20B-26B) underwent procedures prior to IACUC's approval of the protocol amendment which described these procedures. Rabbits 20B-26B underwent electrolytic model procedures between the period of 8/31-9/15/06. An amendment to add the electrolytic model procedure to the protocol was not approved by IACUC until 9/20/06. IACUC must review and approve significant changes to ongoing animal activities prior to initiation of those activities. IACUC must address this issue. Correct by 3/14/07.

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**Prepared By:**

REBECCA B CHAFEL, D V M USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1071

Feb-06-2007

**Received By:**

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**Date:**

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Feb-06-2007