



## Inspection Report

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CUBIST PHARMACEUTICAL INC

Customer ID: **40469**

Certificate: **14-R-0187**

Site: 001

65 HAYDEN AVE.

CUBIST PHARMACEUTICAL INC

Type: ROUTINE INSPECTION

Date: Jul-22-2009

LEXINGTON, MA 02421

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No USDA covered animals or activities at the time of inspection.

Registrant submitted request to cancel registration 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

Jul-22-2009

**Received By:**

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

**Date:**

**Title:**

Jul-22-2009



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65 HAYDEN AVE.

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Site: 001

CUBIST PHARMACEUTICAL INC

LEXINGTON, MA 02421

Type: ROUTINE INSPECTION

Date: Jan-14-2009

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Facility is in compliance with AWA Regulations and Standards.

There are no USDA covered species 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

Jan-14-2009

**Received By:**

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

**Date:**

**Title:**

Jan-14-2009



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CUBIST PHARMACEUTICAL INC

65 HAYDEN AVE.

Type: ROUTINE INSPECTION

LEXINGTON, MA 02421

Date: Jul-16-2008

**2.31** (c) (1) REPEAT  
**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

**2.31** (c) (2)  
**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

**2.31** (c) (3)  
**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

Section 2.31(c) IACUC Functions. (1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation.

Section 2.31(c) IACUC Functions. (2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation.

Section 2.31(c) IACUC Functions. (3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility. . . .The reports shall be updated at least once every six months upon completion of the required semiannual evaluations.

1. The noncompliant item cited on the last inspection report was not corrected. A review of the research facility's program for the care and use of animals has not been conducted since at least March 2007. [Section 2.31(c)(1), REPEAT NCI]
2. An inspection of the research facility's animal facilities was not conducted for the period ending on or about March 29, 2008. [Section 2.31(c)(2)]
3. Review of the Institutional Animal Care and Use Committee semiannual report dated December 1, 2007: The

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Jul-16-2008

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

Date:

Title:

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evaluation of the animal facilities failed to include a schedule with a date for correcting the minor deficiencies noted in this section of the report. [Section 2.31(c)(3)]

4. A semiannual report for the period ending on or about March 29, 2008, was not submitted to the Institutional Official. [Section 2.31(c)(3)]

In accordance with Animal Welfare Regulations, the Institutional Animal Care and Use Committee (IACUC) is required to conduct a review of the research facility's program for humane care and use of animals and to inspect the animal facilities at least once every six months; and to submit a report of its evaluations to the Institutional Official at least once every six months to ensure the humane care and use of the animals. The evaluations should be conducted and the report submitted within the required interval of time.

Correct by: Item 2, 3, 4> Future semiannual reports.

**2.31** (d) (1) (ii)

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

**2.31** (d) (2)

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

Section 2.31(d) IACUC review of activities involving animals. (2) Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. . . .No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.

1. *Review of the Institutional Animal Care and Use Committee minutes/records of IACUC meetings:* Available records indicated that the principal investigator and other research personnel, who were members of the Institutional Animal Care and Use Committee, participated in IACUC reviews and approval of Research Protocol 0012.

Correct by: Immediately.

**2.31** (e) (2)

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

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**Prepared By:**

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

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1059

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

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2.31 (e) (3)

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

2.31 (e) (5)

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

Section 2.31(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities. . . 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, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available.

Section 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: (2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

Section 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.

Section 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.

1. Review of Research Protocol 0012 that described an infectious disease/antibiotic study involving hamsters.
  - a. The proposal described the use of a pathogen to induce an intestinal infection with associated colitis and diarrhea which may cause more than momentary or slight pain and/or distress to the animals. The narrative description pertaining to the methods and sources used to consider alternatives to procedures that may cause more than momentary or slight pain and/or distress to the animals referenced the use of databases but did not indicate the period covered by the search, and therefore failed to describe a search that was adequate to determine that alternatives were not available. [Section 2.31(d)(1)(ii)]
  - b. The proposal failed to provide a rationale for the number of animals to be used. [Section 2.31(e)(2)]
  - c. The proposal failed to describe the clinical signs/criteria for determining the endpoint for removal of an animal from the study. [Section 2.31(e)(3)]
  - d. The proposal failed to describe the method of euthanasia. [Section 2.31(e)(5)]

The Institutional Animal Care and Use Committee (IACUC) should ensure that a proposal to conduct an animal activity provides the required narrative description of the methods and sources used to consider alternatives to procedures that may cause more than momentary or slight pain and/or distress to the animals. The IACUC should ensure that a proposal includes a rationale for the number of animals to be used. The IACUC should ensure that a proposal includes a complete description of the proposed use of the animals. The IACUC should ensure that a

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**Prepared By:**

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

**Date:**

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proposal includes a description of the method of euthanasia.

Correct by: August 15, 2008.

### 2.33 (b) (2)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:  
(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

1. Expired drugs in the research facility: Animal facility, room 3, wall cabinet, lockbox: Ketamine hydrochloride injection (Ketaset), 100 mg/ml, 10 ml vial, lot #440555, expired 7/2003 (1); Ketamine hydrochloride injection (Ketaset), 100 mg/ml, 10 ml vial, lot #440567, expired 8/2003 (5); Xylazine injection, 20 mg/ml, 20 ml vial, lot #101078, expired 1/2003 (1).

The use of expired drugs, fluids, and medical materials is not considered to be acceptable veterinary practice and may adversely affect animal treatment.

Correct by: Expired drugs to be removed for disposal by July 31, 2008.

### 2.35 (a)

#### RECORDKEEPING REQUIREMENTS.

Section 2.35(a) The research facility shall maintain the following IACUC records: (1) Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations;

1. The minutes for the Institutional Animal Care and Use Committee meeting of April 9, 2008, were not available for examination.

Correct by: : August 15, 2008.

Note: This inspection was conducted at the Waltham site location.

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#### Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1059

Jul-16-2008

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Date:

Title:

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CUBIST PHARMACEUTICAL INC

65 HAYDEN AVE.

Type: ROUTINE INSPECTION

LEXINGTON, MA 02421

Date: Jun-21-2007

**2.31** (c) (1)

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

(1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation;

\*\*\*\*\* The semiannual reviews as conducted does not include a review of the research facilities program for humane care and use of animals. This is just as important as the physical plant review for the animals health and well being.  
Correct by: Next Semiannual Review

**2.31** (c) (3)

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

(3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and Provided, further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency

**Prepared By:**

NORMA JEAN HARLAN, D V M USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1004

Jun-21-2007

**Received By:**

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

**Date:**

**Title:**

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funding that activity;

\*\*\*\*\* The semiannual reports did not reflect if any of the IACUC members had reviewed it. There was no indication that a minority view could be expressed in this report to the institutional official. The report was not signed by a majority of the IACUC members. This must all be accomplished for the report to be in compliance with the regs and meet the intent of protecting the animals in the facility.

Correct by: Next Semiannual Report

### 2.33 (a) (1)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:

(1) Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility

\*\*\*\* This facility presently has a part time contract veterinarian. There is no written Program of Veterinary Care set up indicating the specific care to be provided to the hamsters. There is no definitive timetable for the veterinarians visits, nor records of when he last visited the facility. These must all be maintained to verify that appropriate veterinary care is being provided to the animals.

Correct by: 7/10/07

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**Prepared By:**

NORMA JEAN HARLAN, D V M USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1004

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**Received By:**

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

**Date:**

**Title:**

Jun-21-2007