



Inspection Report

WUXI APPTec INC

Customer ID: **15690**

Certificate: **41-R-0061**

Site: 001

APPTec LABORATORY SERVICES, LLC

2540 EXECUTIVE DRIVE

Type: ROUTINE INSPECTION

ST PAUL, MN 55120

Date: Apr-29-2010

No non-compliant items identified during this inspection.

Inspection conducted with In-Life Supervisor, Facility Veterinarian, Senior Director of Quality Assurance and the Associate Director of In-Life Services.

Exit interview conducted with Associate Director of In-life Services.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Apr-29-2010

Received By:

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

Date:

Title:

Apr-29-2010



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APPTec LABORATORY SERVICES LLC

Customer ID: **15690**

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Site: 001

2540 EXECUTIVE DRIVE

APPTec LABORATORY SERVICES, LLC

Type: ROUTINE INSPECTION

Date: May-20-2009

ST PAUL, MN 55120

No noncompliances identified on this inspection.

Inspection and exit interview conducted with Associate Director In-Life Services and Institutional Official.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

May-20-2009

Received By:

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

Date:

Title:

May-20-2009



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WUXI APPTec INC

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2540 EXECUTIVE DRIVE

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ST PAUL, MN 55120

Date: Aug-18-2008

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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.

Training protocol 08-167, approved April 2008, contains procedures where the principal investigator will be using a vasodilator/sedative to "calm the animal". The protocol did not contain a written narrative describing the methods used to search for alternatives to painful and distressful procedures.

The IACUC needs to ensure that all protocols submitted that involve painful or distressful procedures contain a written narrative describing the methods used to search for alternatives to the painful or distressful procedures. This ensures that animals are not used inappropriately in research.

Ensure all protocols submitted to the IACUC containing painful and distressful procedures contain the necessary written narrative describing the search for alternatives to painful and distressful procedures.

Correct from this time forward. This potential affects 30 animals indirectly.

2.31 (d) (5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually.

There were two protocols reviewed during this inspection, 06-98 approved August 2006 and 00-98 approved May 2006 and amended July 2006, that did not have reviews done at least annually for this year (08) and last year (07) by the IACUC. These protocols are still active.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Aug-18-2008

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

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Title:

Aug-18-2008



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Protocols need to be reviewed at least annually by the IACUC to ensure the IACUC has oversight over animals used in research to ensure their health and wellbeing and to ensure that animals are not used inappropriately in research.

Ensure that all active protocols are reviewed at least annually by the IACUC.

Correct from this time forward. This potentially affects 246 animals indirectly.

Inspection conducted with In Life Technical Manager, Senior Director of Quality Assurance, Vice President of Toxicology and Animal Facility Manager.

Exit interview conducted with Institutional Official, In Life Technical manager, Animal Facility Manger, Senior Director of Quality Assurance and Senior Quality Auditor.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Date:

Aug-18-2008

Received By:

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

Date:

Aug-18-2008

Title:



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Certificate: **41-R-0061**

Site: 001

APPTec LABORATORY SERVICES, LLC

2540 EXECUTIVE DRIVE

Type: ROUTINE INSPECTION

SAINT PAUL, MN 55120

Date: Aug-08-2007

No noncompliances identified on this inspection.

Inspection conducted with the IACUC Chair, the Director of QA and a QA Auditor.

Exit interview conducted with IACUC Chair.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Aug-08-2007

Received By:

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

Date:

Title:

Aug-08-2007