



Inspection Report

AMPHASTAR LABORATORIES, INC.

Customer ID: **321451**

Certificate: **93-R-0528**

Site: 001

11570 6TH STREET

AMPHASTAR LABORATORIES, INC.

Type: ROUTINE INSPECTION

Date: Nov-23-2009

RANCHO CUCAMONGA, CA 91730

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d)(1)(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;

-Protocol reviewed do not have this section discussed in their animal study to ensure adequate welfare of the animals. The principal investigator has not considered alternative procedures that may cause more than momentary or slight pain or distress to animals in a written narrative description of the methods and sources used to determine that alternatives were not available. Facility shall ensure that appropriate searches are done to minimize pain and discomfort to the animals. APHIS Policy 12 is recommended as a guide to comply with this requirement and a copy given to facility.

CORRECT BY DECEMBER 23, 2009

2.31 (d) (1) (iii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d)(1)(iii) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments;

-The dog protocol reviewed missed a duplication statement assuring that their study do not unnecessarily duplicate previous experiment. Facility shall ensure that the principal investigator has a written assurance that the activities do not unnecessarily duplicate previous experiments. CORRECT BY DECEMBER 23, 2009.

Above items were discussed with management.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5001

Nov-23-2009

Received By:

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

Date:

Title:

Nov-25-2009



Inspection Report

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Customer ID: **321451**

Certificate: **93-R-0528**

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11570 6TH STREET

AMPHASTAR LABORATORIES, INC.

Type: ROUTINE INSPECTION

Date: Jun-10-2009

RANCHO CUCAMONGA, CA 91730

Facility was registered May 13, 2009 and there are no animals at this time

No non-compliant items identified this inspection.

Note: PVC and IACUC was discussed with Vice President.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5001

Jun-10-2009

Received By:

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

Date:

Title:

Jun-10-2009