USDA

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

Amphastar Laboratories Inc.
11570 6th Street
Rancho Cucamonga, CA 91730

Customer ID: **321451**

Certificate: **93-R-0528**

Site: 001

AMPHASTAR LABORATORIES, INC.

Type: ROUTINE INSPECTION

Date: 06-OCT-2015

2.31(e)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC approved pilot protocol involving rabbits did not contain an adequate rationale for the appropriateness of the species or the numbers of animals to be used for that activity. The protocol stated that 8 rabbits would be used but there was no rationale provided for why these were the numbers needed to make the procedures valid. An explanation is needed to justify these numbers, including factors such as how the numbers were generated, and why the numbers are necessary and / or statistically significant. The rationale for the appropriateness of the species and the number of animals to be used in a study is an important component of protocols that utilize animals. The rationale approved by the IACUC should provide assurance that the appropriate species and number of animals is being used to obtain the information the activity is designed to provide. In addition to assuring that the minimum number of animals is used to obtain the desired information, the rationale should also ensure that enough animals are used to make the activity worthwhile. It is the responsibility of the IACUC to ensure that proposals to conduct activities in ongoing activities involving animals contain rationales that explain the appropriateness of the number of animals to be used in those activities.

To be corrected on all future protocols.

2.33(b)(1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Throughout the facility, there were multiple open and expired bags of saline available for use. In the dog treatment area, a majority of the injectable drugs were expired: Atropine 10/11, Lidocaine 8/14, Acepromazine 1/15 and Bupivacaine 8/15. The expired drugs were on the regular storage shelves (not separated or labeled as expired) and there were no unexpired medications available. There was no indication that the expired drugs had been used recently on any covered species. Use of expired injectable drugs poses a risk to the animals, and is not considered standard of practice for species covered under the Animal Welfare Act.

To be corrected by October 25, 2015

2.33(b)

Prepared By:	KATHARINE FRANK, D V M USDA, APHIS, Animal Care	Date: 09-OCT-2015
Title:	VETERINARY MEDICAL OFFICER 6091	

Received by Title:	SENT BY EMAIL	Date: 09-OCT-2015

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Identification of which animal is in which enclosure and a system to communicate health concerns regarding a particular animal are an important part of providing adequate veterinary care. The cage cards or post it notes for the rabbits did not indicate a tattoo or identification number, only what compound the animal had been given. If the cards are switched during cage cleaning, or the rabbit is put back in a different cage, there is no way to visually confirm that the cage card matches the rabbit (although the rabbit has a unique tattoo). The dogs did not have a identification or cage card available.

A system must be in place to accurately identify the animal in the enclosure and communicate health concerns among the staff and the veterinarian.

To be corrected by October 25, 2015

3.50(c)

FACILITIES, GENERAL.

Several sealed bags of food were stored directly on the floor of the main procedure room, which does not adequately protect the food from the possibility of infestation or contamination by vermin. Food bags should be stored off the floor in order to protect them from infestation or contamination by vermin and to clean around them without contaminating the food with cleaning products.
In the rabbit housing room, the feed bin did not have a milled date or an expiration date to indicate that the food was wholesome, as is required in the facilities SOP.

To be corrected by October 25, 2015

3.131(c)

SANITATION.

The following was noted in the primary procedure room and in the hallway:
The countertops of the primary procedure room were cluttered, with cardboard boxes holding medical supplies, which cannot be readily sanitized. The chairs in the procedure room were fabric covered, and therefore could not be cleaned and sanitized and could collect fur from the rabbits that were brought into the room. There were needle caps, open eppendorf tubes and open bottles of water present in the procedure area.
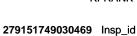There was a sling for larger animals that was sitting in the hallway outside the dog runs. According to the facility, they have not used dogs in a protocol for 6 months to a year, but the sling was covered in fur and debris.

		Date:
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A system to ensure the sanitation of the procedure rooms and animal equipment is important to prevent the spread of disease and maintain healthy animals.

To be corrected by October 25, 2015

An exit briefing was conducted with the facility personnel by Dr. Katharine Frank and Dr. Alexandra Andricos

Additional Inspectors

Andricos Alexandra, Veterinary Medical Officer

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
321451	93-R-0528	001	AMPHASTAR LABORATORIES, INC.	06-OCT-15

Count	Scientific Name	Common Name
000002	*Canis lupus familiaris*	DOG ADULT
000022	*Oryctolagus cuniculus*	EUROPEAN RABBIT
000024	**Total**	