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### **Inspection Report**

Neosome Life Sciences Llc 3 Forbes Road Lexington, MA 02421 Customer ID: 503489

Certificate: 14-R-0215

Site: 001

NEOSOME LIFE SCIENCES LLC

Type: ROUTINE INSPECTION

Date: 24-JUN-2019

#### 2.31(c)(7)

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

Two studies were conducted on an IACUC approved protocol from July 2018 - October 2018.

- 1) The protocol describes humane endpoints for the animals on study, which include an upper limit for tumor size. If an endpoint is reached, the protocol states that the animal is to be removed from the study and humanely euthanized. One animal on study from July 2018 to August 2018 was identified with a tumor that exceeded the upper size limit described in the protocol. This animal was maintained on study and received a test compound after having reached this humane endpoint. Deviation from the IACUC approved endpoints can lead to compromised welfare of the affected animal. Failure to remove this animal from study once the endpoint was reached constituted a significant change without IACUC review or approval
- 2) This protocol indicates that animal weights are to be monitored twice weekly while on study, with more frequent monitoring instituted if weight loss is identified. On review of available health monitoring records, weights were routinely monitored only once per week. 7 animals were identified to have weight loss while on study, and no increased frequency of monitoring was instituted as required by the protocol. Deviation from the IACUC approved monitoring compromises the ability of investigators to identify problems of animal health or welfare. Failure to monitor these animals in accordance with the protocol constituted a significant change without IACUC review or approval.

Any significant change in ongoing activities regarding the care and use of animals must be reviewed and approved by the IACUC prior to being instituted.

Corrected at the time of inspection.

This inspection and initial exit interview was conducted on June 24th, 2019 with a facility representative. A final exit interview was conducted with facility personnel on June 26th, 2019.

Prepared By:KARR EILIS, D V MUSDA, APHIS, Animal CareDate:<br/>26-JUN-2019

Title: VETERINARY MEDICAL OFFICER 6127

Received by Title: DIRECTOR, PRECLINICAL RESEARCH Date:

26-JUN-2019



## United States Department of Agriculture Animal and Plant Health Inspection Service

Customer:

503489 Inspection Date: 24-JUN-19

# **Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection
503489	14-R-0215	001	NEOSOME LIFE SCIENCES LLC	24-JUN-19

No Animals were Inspected.

**Scientific Name Common Name** Count 000000 NONE NONE

000000 Total