



Inspection Report

Valley Biosystems
P.O. Box 2216
West Sacramento, CA 95691

Customer ID: **18820**
Certificate: **93-R-0479**
Site: 001
VALLEY BIOSYSTEMS

Type: FOCUSED INSPECTION
Date: 06-OCT-2022

2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).

The Institutional Animal Care & Use Committee (IACUC) approved protocol 18-021 described implantation surgery "opening skin/muscle layers to expose the skull", perform craniotomies and implanting the base. The protocol did not describe removing portions of the skull to attach the base. On 28 November 2018 there was an unintended post surgical outcome of neurological side effects and seizures the IACUC addressed with the sponsor on 4 December 2018, followed by an IACUC meeting on 5 December 2018. The sponsor did not document the surgical complications from shaving the skull nor communicate them effectively to the facility until after the animal was provided veterinary care. The IACUC documented the adverse effects in a letter to the sponsor, but did not amend protocol 18-021 to document the significant change in the protocol and include the complete description of what the IACUC approved.

During the IACUC meeting considering the protocol the surgical procedure was discussed, specifically improving outcomes from previous similar protocols, but it did not list neurological deficits and seizures as a potential adverse outcomes. After this adverse outcome, the protocol/amendment template was modified to add potential adverse outcomes of the research activities to the IACUC approved protocol.

Prepared By: KATHARINE FRANK
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL
OFFICER

Date:
31-OCT-2022

Received by Title: IACUC Representative

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Corrected at the time of inspection.

This inspection and exit interview were conducted with the IACUC Chair and Attending Veterinarian.

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United States Department of Agriculture
Animal and Plant Health Inspection Service

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
18820	93-R-0479	001	VALLEY BIOSYSTEMS	06-OCT-2022

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	