



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

May 6, 2021

Re: Animal Welfare Assurance
#A3152-01 (OLAW Case 1C)

James Weyhenmeyer, Ph.D.
Vice President for Research
Auburn University
(b) (4) Sanford Hall
Auburn University, AL 36849-0001

Dear Dr. Weyhenmeyer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 21, 2021 letter reporting an adverse event at Auburn University. According to the information provided, OLAW understands that on March 8, 2021, a notification from Envigo was received regarding that a lot of Adjusted Calorie Diet did not contain thiamine and should not be used to feed mice. The affected lot was removed immediately however on March 30, 2021, progressive neurological signs were reported in 18 mice being fed the replacement lot of diet that resulted in the animals being euthanized. Blood samples for pathogen testing were negative. After two conversations with Envigo, it was discovered that the replacement diet was also thiamine deficient and the original communication letter did not identify the replacement lot as thiamine deficient. A third lot of nutritionally complete diet was implemented on April 7, 2021 with no neurological impairment noted thus far. The study is PHS funded.

OLAW appreciates the prompt consideration of this matter by Auburn University which is consistent with the philosophy of institutional self-regulation. OLAW appreciates the transparency in communication of this adverse event and is satisfied that appropriate steps have been taken to investigate this incident to attempt to prevent recurrence. Please contact us with any further questions or concerns.

Sincerely,

Nicole L. Lukovsky-
akhsanov -S

Digitally signed by Nicole L.
Lukovsky-akhsanov -S
Date: 2021.05.06 14:11:27 -04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



AUBURN UNIVERSITY
OFFICE OF THE VICE PRESIDENT FOR
RESEARCH AND ECONOMIC DEVELOPMENT

April 21, 2021

Dr. Brent Morse
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-7982

Assurance Number: D16-00092 (A3152-01)

Dear Dr. Morse,

We are providing a report of an adverse event at Auburn University. Our institution has also been affected by the situation involving the formulation of feed by a commercial vendor.

On March 8, 2021, we received a notification letter from Envigo informing us that a lot of Adjusted Calorie Diet (42% from fat) did not contain thiamin and should not be used. We immediately removed the affected lot and replaced it with food from another lot that was in stock at our facility.

On March 30, 2021 neurologic signs were identified in mice being fed the replacement lot of Envigo diet. The neurologic signs were progressive and resulted in animals being euthanized. On April 2, 2021, a blood sample from an affected animal was sent for pathogen testing and the Attending Veterinarian placed a call to the Envigo nutritionist. Pathogen testing was negative for all agents tested. After two conversations with the Envigo nutritionist on April 7th, it was discovered that the replacement diet implemented on March 8th was also thiamin deficient and was likely the cause of the neurologic signs. Unfortunately, the original communication letter had not identified the replacement lot as also being thiamin deficient.

A third lot of Envigo diet known to be nutritionally complete was implemented on April 7th. Thus far, no neurologic problems have been observed in the animals being fed this diet.

A total of 18 mice have been impacted by this situation.

This project is funded by NIH Grant 5R01HL125279-05 (Award Number).

If additional information is required, please contact the Office of Research Compliance at IACUCAdmin@auburn.edu.

Sincerely,

(b) (6)

James Weyhenmeyer, Ph.D.
Auburn University Institutional Official

Terry Brandebourg, Ph.D.
Auburn University IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 23, 2021 7:49 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: AU Report

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Thursday, April 22, 2021 8:15 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: James Weyhenmeyer <jweyhenmeyer@auburn.edu>; Niki Johnson <johnsnl@auburn.edu>; Terry Brandebourg <tdb0006@auburn.edu>
Subject: AU Report

Good morning,
Please see the attached report from Auburn University (D16-00092/A3152-01) concerning an adverse event.

If you have any questions or need additional information, please contact us at IACUCAdmin@auburn.edu.

Thank you.

(b) (6)

The information transmitted in this message and attachments, if any, is intended only for the person or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure under applicable law. Any review, transmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from your computer.