



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

August 9, 2017

Re: Animal Welfare Assurance
#A4294-01 (OLAW Case E)

Dr. Steven M. Musser
Deputy Director for Scientific Operations
Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Musser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 2, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the FDA Center for Food Safety & Applied Nutrition, following up on an initial telephone report on June 30, 2017. According to the information provided, OLAW understands that the Attending Veterinarian (AV) euthanized a chicken by cervical dislocation without using a Burdizzo instrument which is contrary to the protocol. The bird was euthanized in front of other chickens which is contrary to institutional policy. The AV had been involved in previous noncompliant incidents.

The corrective actions consisted of issuing a letter describing the incident to the AV, issuing a letter to the Principal Investigator involved stating that not reporting the incident constituted noncompliance, having a Post Approval Monitor (PAM) or Institutional Animal Care and Use Committee (IACUC) member observe technical procedures performed by the AV, requiring the AV to report the conduct of an emergency procedure to the PAM and IACUC chair, requiring the AV to meet with the IACUC chair or member prior to performing euthanasia, and monitoring the conduct of euthanasia by the AV. Enhanced oversight of the AV will continue until the IACUC determines that it is no longer needed.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair



AUG 02 2017

Axel V. Wolff, DVM
Director, Division of Compliance Oversight
MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892

Re: Assurance A4294-01 - Non-compliance to Animal Program Standard Operating Procedures and Study Protocol

Dear Dr. Wolff:

The U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN), is conducting research on *Salmonella* in chickens. On Monday, June 26, 2017, the Attending Veterinarian was asked by the Principal Investigator (PI) to examine a study chicken that was lying on the floor of the cage. On June 28, 2017, a decision was made by the Attending Veterinarian and the PI to euthanize the chicken. It came to the attention of the Institutional Animal Care and Use Committee (IACUC) Chairperson that the Attending Veterinarian euthanized the chicken by cervical dislocation without use of a Burdizzo instrument, and did so in a room housing additional chickens. This was witnessed by the PI.

The euthanasia Standard Operating Procedure (SOP) for the CFSAN animal research program clearly describes euthanasia for chickens using a Burdizzo instrument, something that is also indicated in the PI's protocol. Moreover, in the CFSAN animal research program, animals are not to be euthanized in direct view of other study animals, in order to avoid or minimize discomfort and distress to the surrounding animals.

The CFSAN IACUC Chairperson contacted Dr. Axel Wolff of the Office of Laboratory Animal Welfare (OLAW) and reported this incident on June 30, 2017. This incident was the third non-compliance issue involving the Attending Veterinarian that necessitated notification of OLAW. Dr. Wolff stated that the IACUC oversees the veterinary care of the animal program and the IACUC

U.S. Food & Drug Administration
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5001 Campus Drive
College Park, MD 20740

can establish sanctions on the Attending Veterinarian since there is a pattern of non-compliance. A formal letter of the record of events was requested by OLAW.

This document is the final record of events that was requested by OLAW.

FDA's response to address the non-compliance issues are as follows:

1. A letter was sent to the Attending Veterinarian describing the non-compliance issues. A copy of this letter will be kept on file.
2. A letter was sent to the PI indicating that the failure to report the conduct of the Attending Veterinarian is considered a non-compliant event. A copy of this letter will be kept on file.
3. Any technical procedures performed by the Attending Veterinarian on any animal in the CFSAN Animal Facilities will be monitored by the Post Approval Monitor (PAM) or designated IACUC member. The Attending Veterinarian must notify the PAM and the IACUC Chairperson in writing at least 48 hours prior to performing a procedure. If animal emergencies occur, the Attending Veterinarian must notify the PAM and IACUC Chairperson in writing as soon as possible. Failure of the Attending Veterinarian to notify the PAM or IACUC about a procedure will be considered non-compliant event.
4. If the Attending Veterinarian is going to perform euthanasia procedures, the Attending Veterinarian must first meet with the IACUC Chairperson or designated IACUC member to review the SOP for euthanasia. If an animal emergency occurs, the Attending Veterinarian must notify the IACUC Chairperson in writing as soon as possible. The Attending Veterinarian will be monitored by the PAM or designated IACUC member while performing the euthanasia procedure. Failure of the Attending Veterinarian to notify the PAM or IACUC about performing a euthanasia procedure will be considered a non-compliant event.

Enhanced monitoring of the Attending Veterinarian will continue until the IACUC feels that the Attending Veterinarian can perform technical procedures on animals without monitoring. The FDA's Center for Food Safety and Applied Nutrition is committed to protecting the welfare of animals used in research and greatly appreciates the guidance and assistance provided by the Office of Laboratory Animal Welfare in this regard. Should you have any questions regarding this report, please contact the IACUC Chairperson via e-mail ((b) (6) @fda.hhs.gov) or telephone (b) (6)

Sincerely,

A handwritten signature in black ink, appearing to read "Steven Musser", with a long horizontal flourish extending to the right.

Steven Musser, Ph.D.
Deputy Director for Scientific Operations
Center for Food Safety
and Applied Nutrition

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, August 03, 2017 2:34 PM
To: Musser, Steven M (FDA/CFSAN); OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) (FDA/CFSAN); (b) (6) (FDA/CFSAN)
Subject: RE: Assurance report A4294-01

Thank you Dr. Musser,

Doctor Wolff will send an official response soon.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Musser, Steven M [mailto:Steven.Musser@fda.hhs.gov]
Sent: Thursday, August 03, 2017 2:16 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) (FDA/CFSAN) (b) (6) @fda.hhs.gov; (b) (6) (FDA/CFSAN)
<deborah.johnson@fda.hhs.gov>
Subject: Assurance report A4294-01

Dr. Wolff,

I am following up with an official response to an incident reported to OLAW on June 30, 2017. This document (attached and sent by mail) will serve as the final record of events for the incident, along with FDA's response to address non-compliance issues. Should you have any additional questions regarding the incident or this report, please contact our IACUC Chairperson, (b) (6) at (b) (6) @fda.hhs.gov or (b) (6)

Regards,

Steve

Steven M. Musser, Ph.D.
Deputy Center Director for Scientific Operations
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: (b) (6)

Steven.Musser@fda.hhs.gov



Initial Report of Noncompliance

By: *aw*Date: *6/30/17*Time: *1:45*Name of Person reporting: *(b) (6)*Telephone #: *(b) (6)*

Fax #:

Email:

Name of Institution: *FDA CFSAN*

Assurance number: _____

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

AV improperly euthanized a chicken. Other problems noted w/ AV before

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Counsel

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____