



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) 402-7065

February 11, 2019

Re: Animal Welfare Assurance
#A4300-01 [OLAW Case G]

Dr. Peter Marks
Director, Center for Biologics and Research
FDA – White Oak Consolidated Animal Program
10903 New Hampshire Avenue, Bldg. 71
Silver Spring, MD 20993

Dear Dr. Marks,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 6, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the FDA White Oak Consolidated Animal Program, following up on an initial telephone report on January 11, 2019. According to the information provided, OLAW understands that one rat died and one was moribund due to lack of food. The animals had been weaned by an investigator and given a small amount of food which was to be topped off by an animal caretaker. This did not occur and the problem was not communicated to, or noted by, the weekend animal care staff during health checks.

The corrective actions consisted of disciplining the animal care staff responsible and retraining all husbandry staff on the appropriate conduct of health checks, communicating instructions, and monitoring food levels. The supervisor will ensure that husbandry duties have been completed on weekends and holidays and any problems will be communicated to the caretaker and documented. The supervisor will ensure that all animal care problems have been addressed before leaving for the day.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



**White Oak Consolidated
Animal Program**

A4300
Food and Drug Administration
10903 New Hampshire Ave. Bldg 71
Silver Spring, MD 20993

Date: February 6, 2019

From: (b) (6) Ph.D., Chairperson
White Oak Consolidated IACUC

(b) (6)

Through: Peter Marks, MD, PhD, CBER Institutional Official

Subject: Incident Report

To: Axel V. Wolff, MS, DVM, Director, Division of Compliance Oversight, OLAW, NIH

Details:

An investigator weaning rats on Thursday November 8, 2018 did not have an adequate supply of feed for the seven cages being setup, so distributed the available feed equitably across all cage feed hoppers. The investigator notified the animal caretaker on duty of deficient feed levels and requested that the hoppers be supplemented with feed to raise the level. This instruction was disregarded by the caretaker that afternoon and the next day, and the instruction about adding food was not communicated effectively among the animal care staff, so as a consequence, no action was taken. Despite daily animal health care checks, the low or absent levels of feed in the seven cages was also not noticed over the long Veterans Day weekend. The following day, November 13, one cage was identified with a dead weanling rat and a moribund rat. Rats in the other cages appeared normal.

The incident was relayed by phone to OLAW on January 8.

Corrective Actions:

Disciplinary action was taken regarding the responsible employees, and the entire Priority One staff was retrained on performance of health checks, communicating instructions, and monitoring cage feed levels. In addition, since twice-daily health checks cannot be performed with the existing contract on weekends and holidays, the on-duty contract manager/supervisor has an additional responsibility to complete a check that identifies observed deficiencies in work performance. Any such deficiencies are now communicated verbally to the responsible animal caretaker and documented on the weekend/holiday form. Before leaving for the day, the manager/supervisor ensures that animal-care-related issues have been addressed or corrected. Although this particular incident was caused by worker carelessness and failure to follow instructions, this supervisory enhancement is expected to improve regular communication and prevent future incidents like this one.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 06, 2019 3:42 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Dennis, John (FDA/CBER); (b) (6) FDA/CBER; (b) (6) FDA/CBER; Marks, Peter (FDA/CBER); WO AP IACUC; (b) (6) FDA/CBER (CTR)
Subject: RE: Incident Report for FDA White Oak Consolidated Animal Program Assurance A4300-01

Thank you for providing this final report Ms. (b) (6). We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
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: (b) (6) [mailto:(b) (6)@fda.hhs.gov]
Sent: Wednesday, February 06, 2019 1:38 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Dennis, John (FDA/CBER) <John.Dennis@fda.hhs.gov> (b) (6) FDA/CBER (b) (6)@fda.hhs.gov; (b) (6) FDA/CBER (b) (6)@fda.hhs.gov; Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; WO AP IACUC <WOAPIACUC@fda.hhs.gov> (b) (6) FDA/CBER (CTR) (b) (6)@fda.hhs.gov
Subject: Incident Report for FDA White Oak Consolidated Animal Program Assurance A4300-01

The White Oak Consolidated (WOC) Animal Program and IACUC, is self-reporting a non-compliance incident and corrective action plan for Animal Welfare Assurance A4300-01. Please review the attached Incident Report.

Please contact Dr. John Dennis, (b) (6) if you have any questions.

Thank you,

(b) (6)
WOC IACUC Administrator
Division of Veterinary Services
(b) (6)



Initial Report of Noncompliance

By: *aw*Date: *1/11/19*Time: *9:15*Name of Person reporting: *(b) (6)*Telephone #: *(b) (6)*

Fax #:

Email:

Name of Institution: *FDA/CBER*Assurance number: *A4300*Did incident involve PHS funded activity? *Yes*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

1 Rat dead 1 moribund because caretaker did not fill food hopper. Low food supply. Rats were weaned + no food given.

Species involved: *Rat*

Personnel involved:

Dates and times:

Animal deaths: *1*

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

Retrain, observe PIs weaning animals.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____