



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

December 3, 2021

Re: Animal Welfare Assurance
A3368-01 [OLAW Case 11L]

Dr. Nadine Connor
Associate Vice Chancellor
for Research Policy and Compliance
University of Wisconsin-Madison
(b) (4) Bascom Hall – 500 Lincoln Drive
Madison, WI 53706

Dear Dr. Colman and Dr. Connor,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 8, 2021 letter providing additional requested information regarding corrective and preventative measures taken following incident A3368-01, OLAW Case 11L.

According to the additional information provided, OLAW understands that several corrective and preventative measures were taken. A new SOP was created detailing requirements for proper labeling, checking, and disposition of expired drugs. Veterinary technicians were reminded to check the supply of expiration date stickers during routine checks of their assigned areas, and a reminder was included in an institutional newsletter. Retraining was also provided regarding double checking expiration dates at two monthly staff meetings.

OLAW appreciates the consideration of this matter by the University of Wisconsin-Madison which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S
Digitally signed by Robyn M.
Engel -S
Date: 2021.12.03 13:33:48 -05'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact

Dr. Robert M. Gibbens, USDA, APHIS, Animal Care



Office of the Vice Chancellor for
Research and Graduate Education
UNIVERSITY OF WISCONSIN-MADISON

November 8, 2021

Dr. Robyn M. Engel, DVM, DACLAM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7892

Dear Dr. Engel:

In our letter to you dated July 9, 2021 (A3368-01, OLAW Case 11L), we reported an incident in which two adult macaques received doses of expired oral acetaminophen for 36 days because the expiration date label on the bottle was incorrect. In this letter we stated that a root cause analysis was conducted that found that the institution's standard expiration dots need to be readily available in all animal areas and the "opened vial" stickers need to be checked more closely.

In your response, dated July 29, 2021, you stated that the root cause analysis identified possible corrective measures, but it was not clear what actions had been taken to prevent recurrence. The actions we took to prevent recurrence were:

- To create a new SOP called "Proper Labeling, Checking, and Disposition of Expired Drugs and Medical Materials" that details all of the requirements;
- To remind veterinary technicians that they need to check the supply of stickers during the routine checks of their assigned areas;
- To provide retraining regarding double checking expiration dates at two monthly staff meetings; and
- To provide a reminder regarding double checking expiration dates in the Summer Newsletter.

The LSVAC ACUC is not aware of any recurrence of this type of incident in research under its purview to date. If you have further questions, please feel free to contact either of us or Dr. Janet Welter.

Sincerely,

(b) (6)

Ricki Colman, Ph.D.
Chair, LSVAC ACUC

(b) (6)

Nadine P. Connor, Ph.D.
Professor and Oros Family Chair in Communication Sciences & Disorders
Associate Vice Chancellor for Research Policy & Compliance
Institutional Official

xc:

(b) (6)

Janet Welter
AAALAC-I

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 19, 2021 7:01 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident Report from Nadine Connor @ UW-Madison

Thank you for this report. Dr. Engel will send a response soon.

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

From: (b) (6)
Sent: Wednesday, November 17, 2021 4:33 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Engel, Robyn (NIH/OD) [E] <robyn.engel@nih.gov>
Cc: RICKI COLMAN <rcolman@primate.wisc.edu>; AAALAC International <accredit@AAALAC.org>; Nadine Connor <nadine.connor@wisc.edu>; (b) (6) Janet Welter <welter@rarc.wisc.edu>
Subject: Incident Report from Nadine Connor @ UW-Madison

Dr. Morse/Dr. Engel:

Please see the attached incident final report from Nadine Connor @ UW-Madison. Thanks!

(b) (6)





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FOR EXPRESS MAIL:

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

July 29, 2021

Re: Animal Welfare Assurance
A3368-01 [OLAW Case 11L]

Dr. Nadine Connor
Associate Vice Chancellor
for Research Policy and Compliance
University of Wisconsin-Madison
(b) (4) Bascom Hall – 500 Lincoln Drive
Madison, WI 53706

Dear Dr. Connor,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 9, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Wisconsin-Madison. Your letter supplemented the information contained in an initial telephone report to this office on July 8, 2021. According to the information provided, OLAW understands that two adult macaques received doses of expired oral acetaminophen for 36 days, because the expiration date label on the bottle was incorrect. The person who opened the bottle could not find the institution's standard expiration dot to place on the vial and used an "opened vial" sticker instead. The individual mislabeled the expiration date on the "opened vial" sticker. No adverse effects to the animals involved were noted. The macaques involved in this incident were supported by PHS funds.

A root cause analysis was conducted which found that the institution's standard expiration dots need to be readily available in all animal areas and that "opened vial" stickers need to be checked more closely. The Institutional Animal Care and Use Committee (IACUC) discussed the incident at a convened meeting and considered the corrective steps taken to be appropriate.

OLAW appreciates the consideration of this matter by the University of Wisconsin-Madison which was consistent with the philosophy of institutional self-regulation. However, some clarification is needed. Please provide a brief description of the corrective steps taken. The root cause analysis identified possible corrective measures, but your letter did not describe what actions were taken to prevent recurrence. **Please provide the requested information to OLAW by August 27, 2021.**

Sincerely,

Robyn M. Engel - Digitally signed by Robyn M.
Engel - S
Date: 2021.07.30 07:23:22 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact



July 9, 2021

Dr. Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7892

Dear Dr. Morse:

The University of Wisconsin-Madison, in accordance with Assurance **A3368-01** and PHS Policy IV.F.3, provides this report of an incident first reported to you via telephone by Dr. Janet Welter on July 8, 2021.

In this incident, for 36 days two adult macaques received doses of expired oral acetaminophen because the expiration date written on the bottle was mislabeled. A root cause analysis revealed that the individual who opened the bottle of acetaminophen could not find the appropriate standard expiration dot to place on the vial, used an "opened vial" sticker instead, and mislabeled the expiration date. Subsequently, everyone who used the bottle only looked at the expiration date noted on the open vial sticker. The analysis also revealed that the standard expiration dots need to be readily available in all animal areas and that open vial stickers need to be checked more closely. No adverse effects to the animals involved were noted. The animals involved were supported by PHS funds.

The LSVC ACUC discussed this incident in full committee and considered the corrective steps taken appropriate. If you have further questions, please feel free to contact either of us or Dr. Janet Welter.

Sincerely,

(b) (6)

Ricki Colman, Ph.D.
Chair, LSVC ACUC

(b) (6)

Nadine P. Connor, Ph.D.
Associate Vice Chancellor for Research Policy & Compliance
Institutional Official

xc: (b) (6)

Janet Welter
AAALAC-I

Research Animal Resources Center

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 19, 2021 7:38 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident Reports from Nadine Connor @ UW-Madison

Thank you for these reports. We will send responses soon.

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

From: (b) (6)
Sent: Monday, July 12, 2021 11:51 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALAC International <accredit@AAALAC.org>; Nadine Connor <nadine.connor@wisc.edu>; (b) (6)
(b) (6) RICKI COLMAN <rcolman@primate.wisc.edu>; Janet Welter <welter@rarc.wisc.edu>
Subject: Incident Reports from Nadine Connor @ UW-Madison

Dr. Morse:

Please see the attached incident final reports from Nadine Connor @ UW-Madison. Thanks!

(b) (6)