



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
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Office of Laboratory Animal Welfare
Rockledge One, Suite 360
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Bethesda, Maryland 20817
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April 3, 2018

Re: Animal Welfare Assurance
A3085-01 [OLAW Case 1E]

Dr. Theodore F. Taraschi
Vice President for Research
Thomas Jefferson University
1020 Locust Street
Philadelphia, PA 19107

Dear Dr. Taraschi,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 26, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Thomas Jefferson University, following up on an initial December 21, 2017 email notification. According to the information provided, OLAW understands that during a routine laboratory audit it was identified that expired pentobarbital was administered as an anesthetic for a terminal procedure to a total of ten mice.

The corrective actions consisted of immediately discarding the expired drug, discussing the noncompliance with the Principal Investigator (PI) and a research associate, providing copies of the IACUC Management of Controlled Substances Policy to the PI and laboratory personnel and the PI instructing laboratory staff to refrain from using expired drugs in animals which was further emphasized by the Post-Approval Monitor during a follow-up meeting.

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,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

(b) (6)

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Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, March 27, 2018 11:29 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Theodore Taraschi
Subject: RE: [A3085-01] TJU Final Report - 171221

Thank you for sending this report. We will send an official response soon.

Regards, Brent Morse

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

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From: (b) (6)@jefferson.edu]
Sent: Monday, March 26, 2018 6:13 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Theodore Taraschi <Theodore.Taraschi@jefferson.edu>
Subject: [A3085-01] TJU Final Report - 171221

Dear Dr. Morse and the Office of Laboratory Animal Welfare,

On behalf of Dr. Theodore Taraschi, Institutional Official, I am writing to provide the final report for an incident of noncompliance at Thomas Jefferson University. (See attached.) Please don't hesitate to contact us if you have any questions or concerns.

Sincerely,

(b) (6)



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Wolff, Axel (NIH/OD) [E]

A3085-01

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 21, 2017 1:39 PM
To: (b) (6)
Subject: RE: [A3085-01] Preliminary Report - 171221

Thank you for this preliminary report, (b) (6). We will open a new case and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

From: (b) (6)@jefferson.edu]
Sent: Thursday, December 21, 2017 1:28 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)@jefferson.edu>; (b) (6)@jefferson.edu>
Subject: [A3085-01] Preliminary Report - 171221

Dear OLAW,

Please accept this e-mail as a preliminary notification of a reportable offense that has been recently identified at our institution.

Name and Contact Information of Person Reporting:

(b) (6)

Name of Institution: Thomas Jefferson University

Assurance Number: D16-00051 (A3085-01)

Funding Component and If Contacted: To be determined.

Brief Description of Incident (e.g., species, category of personnel involved, dates, times, animal deaths): On December 13, 2017, during a routine laboratory inspection, the use of expired Nembutal® (pentobarbital sodium) in live animals was identified. The expiration date was September 20, 2017. The involved animal use protocol numbers was 01189. Nembutal is a DEA Schedule II Controlled Substance. Use of the pharmaceutical after its expiration date occurred one time on October 30, 2017. This incident involved the use of 0.5 mL of Nembutal, and was administered to an estimated 10 mice. The Nembutal was being used as an anesthetic for a terminal procedure.

Plan and Schedule for Correction and Prevention (if known): The expired pharmaceuticals were confiscated from the laboratory for disposal. The PI and laboratory members were informed that use of expired pharmaceuticals in live animals is strictly prohibited. The PI and laboratory members have been provided copies of the IACUC's Management of Controlled Substances Policy. Additional retraining on proper use and management of controlled substances is pending. Additional preventative actions are being discussed and considered by the IACUC.

Timeframe for Final Report from the Institutional Official: A final report should be submitted within 90 days.

Sincerely,

(b) (6)



(b) (6)

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