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

June 11, 2018

Re: Animal Welfare Assurance
#A3471-01 [OLAW Case 3B]

Dr. Wesley Byerly
Associate Vice President
for Research Compliance
UConn Health
263 Farmington Avenue
Farmington, CT 06030

Dear Dr. Byerly,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 7, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Uconn Health, following up on an initial report on May 17, 2018. According to the information provided, OLAW understands that expired analgesic drugs had been given to eight mice following surgery. The mice did not show signs of pain or distress due to receiving the expired drugs.

The corrective actions consisted of counseling the investigator to discard the expired drug, obtain a new bottle, and not to use any expired anesthetics or analgesics on animals.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair
(b) (6)

UCONN
HEALTH

Dr. Brent Morse
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

June 7, 2018

RE: PHS Assurance A3471-01/D16-00295, UConn Health

Dear Dr. Morse-

I am writing to you to provide a final report of an incident of non-compliance at Uconn Health. You were originally notified of this incident by email from our IACUC Administrator on May 17, 2018.

The original notification informed you that a PI had given mice expired Buprenorphine for post-surgical analgesia. This was found during our semi-annual inspections of the laboratory. The PI was informed that they could not use expired drugs in laboratory animals and was directed to dispose of the Buprenorphine and obtain a new, unexpired vial.

The IACUC reviewed the records associated with this incident and it was determined that 2 cages of mice, 4 mice per cage, had received the expired Buprenorphine. Review of post-surgical monitoring records did not indicate that mice were in any unrelieved pain/distress due to receiving the expired analgesic.

This incident was brought to the attention of the IACUC during the May 31, 2018 IACUC meeting. The IACUC was satisfied that the incident was resolved. The IACUC sent a letter to the PI to remind them that the use of expired drugs for anesthetic or analgesics purposes is prohibited under federal regulations.

This non-compliant activity was not funded by federal PHS funds.

While all efforts were made to deal with this issue in a timely and meaningful manner, I realize there may be questions that arise following your review of this material. Please feel free to contact me at byerly@uchc.edu or at   (b) (6)

Sincerely,

(b) (6)

Wesley G. Byerly, Pharm.D.
Associate Vice President, Research Integrity and Regulatory Affairs

cc: Dr. Joseph Lorenzo, IACUC Chair
       Dr. Kathryn Bayne, AAALAC-i

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Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Monday, June 11, 2018 10:19 AM
To:	(b) (6)
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Final report of non-compliance

Thank you for this report. We will send a response soon.

Axel Wolff

From: (b) (6)@uchc.edu]
Sent: Monday, June 11, 2018 9:46 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final report of non-compliance

Good morning-

On behalf of my Institutional Official, I am sending you a final report of non-compliance that was originally reported to you via email on 5/17/18. This incident involved the use of expired Buprenorphine in mice.

Please let me know if you have any questions or require any additional information.

Thank you and have a wonderful day!

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, May 17, 2018 11:35 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary report of non-compliance

Thank you for this prompt preliminary report (b) (6) We will open a case file and await further information.

Best 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)@uchc.edu]
Sent: Thursday, May 17, 2018 11:00 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Preliminary report of non-compliance

Good morning-

I'm writing on behalf of my Institutional Official to inform you of a non-compliance. During our semi-annual facility inspections, we discovered that an investigator gave expired buprenorphine to some laboratory mice. At the time of inspection, the PI was informed to return the expired buprenorphine and obtain new. This incident will be discussed by our IACUC during our May IACUC meeting and we will submit a final report to OLAW.

Please let me know if you need any further information at this point.

Thank you-

(b) (6)