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

July 2, 2019

Re: Animal Welfare Assurance
A4367-01 [OLAW Case W]

(b)(6)

Centers for Disease Control
1600 Clifton Road NE, Clifton Building
Atlanta, GA 30329

Dear (b)(6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 28, 2019 letter reporting an adverse event caused by human error which negatively impacted rats at the Centers for Disease Control and Prevention National Institute for Occupational Safety and Health. According to the information provided, OLAW understands that nine rats died, and three rats required euthanasia following an approved intratracheal instillation procedure. One additional rat was tested with a sample of reference material and immediately died.

The corrective action consisted of terminating the study and investigating the cause of the deaths. It was determined that a strong salt solution had inadvertently been used for the sample delivery vehicle rather than phosphate buffered saline. To prevent a recurrence the Institutional Animal Care and Use Committee (IACUC) has directed that reagents used in animals are to be separated from those not used in animals, to clearly label agents for use in animals, to allow adequate time for preparation of reagents, and to always double check the reagent before administration.

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

Sincerely,

Axel Wolff, MS, D

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

cc: IACUC Contact

A4367- W

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

PHS Assurance #D16-00687 (A4367-01)

June 28, 2019

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

Dear Dr. Morse,

On May 22, 2019, at the CDC NIOSH-Morgantown facility, during an IACUC-approved intratracheal instillation procedure, six out of sixteen rats were found dead within 10 minutes post-exposure and a seventh rat died while under anesthesia. At that point, the investigator elected to terminate the study and euthanized the remaining two rats in the experimental group until the cause of death was determined. The investigator then immediately reported the adverse event to the Attending Veterinarian, the IACUC Chair, and the IACUC Administrator. The following day, May 23, 2019, two additional rats from the study were found dead and the remaining rat from the exposed groups was euthanized. On May 28, 2019, in an attempt to determine if there was a problem with the samples, one more instillation was conducted using a sample of reference material from the same lot that was known to have no endotoxin and had been routinely used at this dose - the rat died instantly. Upon further investigation, it was discovered that the wrong vehicle had been used for sample preparation, 5 M sodium chloride, instead of phosphate buffered saline (PBS). CDC concluded that the unexpected rat deaths was an isolated incident caused by peracute lung injury from a strongly hypertonic solution (5 M sodium chloride) that was mistakenly used in the particle preparations.

In response to this incident, the CDC-Morgantown IACUC recommended the following corrective actions to prevent recurrence of this type of error:

1) Physically separate reagents approved for use in animals from those reagents not for use in animals, and
2) Place easily recognizable visual cues (bright stickers/ labels) on reagent bottles to identify reagents approved for use in animals, and/or on partitions, boxes or containers holding reagent bottles to distinguish reagents approved for use in animals, and
3) Schedule sufficient time, follow a methodical process for preparations of reagents, and double check the reagent preparation before administering to animals.

The CDC-Morgantown IACUC discussed this adverse event at the June 20, 2019 meeting and voted to report this to OLAW. Upon the corrective actions outlined above, the committee did not feel that any other actions were needed at this time.

Sincerely,

(b)(6)

Centers for Disease Control and Prevention

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 01, 2019 9:12 AM
To: (b)(6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD); Animal Care and Use Program Office (CDC); CDC NIOSH HELD ACUC (CDC)
Subject: RE: Incident report submission for CDC-Morgantown (PHS Assurance #D16-00687(A4367-01))

Thank you for providing this report Dr. Pimentel. 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

From: (b)(6)
Sent: Friday, June 28, 2019 3:57 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6) Animal Care and Use Program Office (CDC) (b)(6); CDC NIOSH HELD ACUC (CDC (b)(6)
Subject: Incident report submission for CDC-Morgantown (PHS Assurance #D16-00687(A4367-01))

Dear Dr. Morse and colleagues,
Please find attached an incident report for submission.

Thank you,

(b)(6)
Centers for Disease Control and Prevention