



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 B 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

January 31, 2018

Re: Animal Welfare Assurance
A3977-01 [OLAW Case C]

Ms. Roxanne Miller
Senior Director St. Paul Operations
WuXi AppTec, Inc.
2540 Executive Drive
St. Paul, Minnesota 55120

Dear Ms. Miller,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 19, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at WuXi AppTec. According to the information provided, OLAW understands that due to the lack of flow meters on CO2 euthanasia chambers, the required gas displacement rates could not be verified to be compliant with the American Veterinary Medical Association Guidelines for the Euthanasia of Animals. The Attending Veterinarian had not noted any problems with CO2 euthanasia and felt that the flow rates were probably within the Guideline parameters.

The corrective action consisted of installing CO2 flow meters at all rodent euthanasia stations, developing standard operating procedures addressing flow rates, and training staff on these procedures.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

Signature

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

cc: IACUC Chair

January 19, 2018

Roxanne Miller
Senior Director of Operations
Institutional Official
WuXi AppTec U.S. Biologics, Advanced Therapies & Medical Devices Manufacturing and Testing
2540 Executive Drive
St. Paul, MN 55120

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff:

WuXi AppTec, in regards to Assurance A3977-01 and PHS Policy IV.F.3., sends this notification of noncompliance in regards to carbon dioxide euthanasia without demonstrated adherence to American Veterinary Medical Association (AVMA) guidelines. This activity was not reviewed and approved by the IACUC.

The incident was first reported to the IACUC, on November 14th, 2017 by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) during a site visit. During the walkthrough, it was noted that the current systems for carbon dioxide euthanasia of rodents could not be proven to follow displacement rates as directed by American Veterinary Medical Association (AVMA) guidelines. Through discussions with the Attending Veterinarian it was determined that no adverse events related to this method of euthanasia (via carbon dioxide) had been observed and it was likely that the flow rate utilized was within AVMA guidelines. This, however, could not be verified due to lack of flow meters.

The following corrective actions were taken to address these exceptions:

On Tuesday November 21st, 2017, carbon dioxide flow meters were installed at all locations within the facility currently in use for euthanasia of rodents. Applicable Standard Operating Procedures (SOPs) have been updated to reflect appropriate flow rates per AVMA guidelines, effective November 29th, 2017, and a group training session was performed on November 29th, 2017.

If there are any questions or concerns regarding this notification, please feel free to reach out via the information below.

Thank you for your consideration of these matters.

Sincerely,

Signature

Roxanne Miller
Senior Director of Operations
Institutional Official
WuXi AppTec U.S. Biologics, Advanced Therapies & Medical Devices Manufacturing and Testing
2540 Executive Drive
St. Paul, MN 55120
roxanne.miller@wuxiapptec.com

2018 JAN 25 PM 2:55

A3977-01

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 01/16/2021