



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
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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
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January 31, 2018

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

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 a deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at WuXi AppTec. According to the information provided, OLAW understands that several rabbit cages are below the sixteen inch minimum height parameter and this exception had not been approved by the Institutional Animal Care and Use Committee (IACUC).

The corrective action consisted of developing a performance standard to allow use of the current size cage based on the fact that most rabbits used at the institution are young or small and are only maintained for up to two weeks. The veterinary staff has not noted any health problems with the rabbits housed in the current cages and for any long term studies, the taller cages will be used. The IACUC approved the exception to the *Guide* and all new caging purchased will be of the taller type.

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

Sincerely,

Signature

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

cc: IACUC Chair

A3977- B

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

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 incidents of housing rabbits in cages under sixteen inches in height. This activity was not reviewed and approved by the IACUC.

The incident was first reported to the IACUC, on November 14th, 2017 by a conversation with the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) during a site visit. During program review, it was noted that some rabbit cages fell below the recommended minimum height of sixteen inches as stated in the *Guide* and that this exception was not officially approved by the IACUC.

The following corrective actions were taken to address this exception:

A memorandum from In-Life Services Management and Attending Veterinarian regarding the use of rabbit caging with heights of fifteen inches was submitted to the IACUC. This memo was reviewed at a convened meeting of the IACUC on November 28, 2017 and provides the following justification;

“Currently, a small portion of rabbit racks within the facility fall under the 16 inch height requirement. We acknowledge this but also consider the performance standard of natural postures and species specific behavior in regards to caging size. The majority of rabbits housed within WuXi AppTec are of short duration (less than two weeks) and young/small in size. If long term studies are to be conducted, animal care utilizes cages with a minimum of 16 inches in height.

Historically the veterinary staff have not witness nor have been notified by any of the animal care or research technicians of any stereotypies or self-trauma that could be attributed to the one inch decrease in cage height.

In Life Services management is aware of the height requirement and all replacement caging purchased moving forward will satisfy the height requirement as stated in the *Guide*.”

The exception to the *Guide* regarding rabbit cage height has been reviewed and approved by the WuXi AppTec IACUC as of November 28th, 2017 and the memo will be incorporated into active IACUC protocol files. 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
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St. Paul, MN 55120
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