From:Gibbens, Robert - APHISTo:Yager, Cody M - APHISCc:Theodorson, Elizabeth C - APHISSubject:Fwd: OLAW Case A3343-2QDate:Thursday, May 2, 2019 2:15:06 PM

Attachments: 2008 001.pdf

Robert M. Gibbens, DVM Director, Animal Welfare Operations USDA, APHIS, Animal Care

From: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>

Sent: Thursday, May 2, 2019 11:21:54 AM

To: gdraetta@mdanderson.org

Cc ; Gibbens, Robert - APHIS

Subject: OLAW Case A3343-2Q

Dear Dr. Draetta,

Attached please find Dr. Brent Morse's final response to OLAW Case A3343-2Q.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards,

Joan

Joan Ward

Program Specialist

Office of Laboratory Animal Welfare

National Institutes of Health

6700B Rockledge Dr., Suite 2500

Bethesda, MD 20892

301-496-7163

wardjoa@od.nih.gov



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:
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6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
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May 2, 2019

Re: Animal Welfare Assurance #A3343-01 (OLAW Case 2Q)

Dr. Giulio Draetta
Chief Scientific Officer
University of Texas MD Anderson Center
1515 Halcombe Boulevard — (b) (4)
Houston, Texas 77030

Dear Dr. Draetta,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated April 24, 2019 reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas MD Anderson Cancer Center. According to the information provided, OLAW understands that on February 22, 2019 two non-human primates developed skin lesions at injection sites after receiving daily subcutaneous administrations of a drug study vehicle possibly due to the pH. Medical treatment was initiated and the lesions were almost completely healed after four weeks of treatment. The protocol to which the animals were assigned is supported by PHS funds.

Corrective and preventive actions included implementing verification of the pH for every batch of the study drug vehicle.

The prompt consideration of this matter by the University of Texas MD Anderson Cancer Center was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

Dr. Robert M. Gibbens, USDA, APHIS, AC