Exhibit 4

4) September 19, 2012 letter from OLAW to Institutional Official (IO) at UW posing specific questions regarding clinical veterinary record keeping, training of research staff, provision of analgesia, and humane endpoints.

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
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Facsimile: (301) 402-7065

September 19, 2012

Re: Animal Welfare Assurance
A3368-01 [OLAW Case 4P]

Name
Title
University of Wisconsin-Madison
Room # Bascom Hall – 500 Lincoln Drive
Madison, WI 53706

Dear Name

The Office of Laboratory Animal Welfare (OLAW) received from the People for the Ethical Treatment of Animals (PETA) an allegation of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wisconsin- Madison. The allegation concerns a cat used in a study supported by the National Institute on Deafness and Other Communication Disorders and was accompanied by copies of clinical records (8/06-12/08), the Animal Care and Use Committee (ACUC) approved protocol (2008), and a procedure log for the study involving cat L005/G07 (4/08-6/08). After reviewing the specific allegations and the supporting documents, OLAW has formulated some questions which are to be addressed by the ACUC responsible for overseeing this study. Please direct the ACUC, avoiding any conflicts of interest, to address the following:

1) What is the policy on the frequency at which treatment and progress records are updated? Who is responsible for animal observations and making notations in the clinical records? Are additional records on an animal's clinical condition kept by the investigator?

2) There are numerous gaps in the clinical record following initial observations such as facial asymmetry (observed 9/19/08 and the next observation recorded 10/6/08). Indicate what type of follow up is to be made and by whom when a clinical abnormality is recorded and at what frequency. Is there an additional form of documentation to verify daily observation of animals?

3) Did this specific study outline humane endpoints for removal of an animal from further research activities? Indicate what actions are taken in response to unanticipated adverse events such as chronic infection.

4) Comment on the provision of analgesia for this cat while on study and on treatment for the chronic scalp infection. Were the injections of buprenorphine given in response to clinical signs of pain or prophylactically?

5) The procedure log for 11/21/08 indicates that a two hour procedure was performed under ketamine and acepromazine and that the anesthesia became light requiring additional injection. The approved protocol states that this injectable cocktail would be used only in procedures lasting 30 minutes or less and that all longer procedures would be performed using inhalant anesthetic (isoflurane). Indicate whether the ACUC approved the conduct of a two hour surgery under injectable anesthesia. If a significant change was implemented without ACUC approval, was any action taken and was this reported to OLAW?

6) The procedure log for 6/11/08 indicates that the anesthetic mask came off and the animal showed signs of waking. If this animal was intubated why did the anesthesia become light when the mask came off and why was the mask used?

7) Provide an explanation on the adequacy and competency of staff involved in the surgeries and their ability to maintain an appropriate plane of anesthesia during the procedures.

8) Provide information on the type of justification investigators are to provide the ACUC for the species and numbers of animals requested. What type of statistical justification is required?

9) Are these studies ongoing? If so, has the ACUC determined that all staff is appropriately trained, that anesthesia is appropriately applied, that animal observations are adequately documented, that humane endpoints are in place, and that animal numbers are appropriately justified? Provide any information on the application of refinement, reduction, or replacement to these types of studies.

10) Provide any additional relevant information to this specific case or any other similar study using cats in hearing studies.

Please provide a final or interim report by October 15, 2012. Feel free to contact me should you have any questions.

Sincerely,

Axel Wolff, M.S., D.V.M.

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc Name, Title