



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Animal Care
Western Region

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December 19, 2008

Clifford R. Roberts, D.V.M.
Office of Research
Mission Bay Genentech Hall
600-16th Street, Suite 272
San Francisco, CA 94143-0407

Dear Dr. Roberts:

Thank you for your letter of May 30, 2008 appealing your USDA inspection report of April 15, 2008. I apologize for the delay in providing a reply. I will address each item in the order presented in your letter.

Item 1- Institutional Animal Care and Use Committee

The inspection of University of California San Francisco was conducted with Dr. Michael Smith, Dr. Marcy Rosendale, UCSF's Compliance Manager, and other members of the UCSF staff, including supervisors from areas inspected.

The exit briefing, describing the findings on the inspection report, was conducted with the IACUC Chairman, Compliance Staff, and the attending veterinarian. All issues were discussed during the inspection and the exit briefing, and the opportunity to provide additional information was provided. During the course of the exit briefing, neither the IACUC Chair, Compliance Staff, nor the attending veterinarian (all of whom are IACUC Committee members and/or attendees at IACUC meetings) mentioned or provided information which would have indicated prior knowledge or actions by the IACUC committee in regards to the animals.

The inspection report did not take into consideration the animal's involvement in the protocol during April 2006, as there were no issues at that time with weight loss or chronic infections. At the time of the inspection and during the exit briefing, the inspectors were not told of a short term terminal study with this animal. Neither the protocol or protocol amendments, nor the investigator, attending veterinarian or IACUC members in attendance, mentioned that this animal was on a short term study.

The inspectors were told by the attending veterinarian that the animal was taken off of the food restriction portion of the protocol because of the weight loss and that the investigator was responsible for providing the animal with his daily feed requirements while the animal was being chaired and working. The distress and discomfort documented by our inspectors appeared to be caused by the weight loss of the animal (during the time mentioned in the inspection report) as well as the infected, malodorous tissues of the skull surrounding the implant. This was considered a non compliance



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because of the weight loss, chronic unresolved infection of the tissue surrounding the implant, and the failure of UCSF to step in and address the animal's health problems.

Contrary to the statement that the animal was on a short term terminal study, the protocol and subsequent amendments do not mention the use of an animal for short term terminal purposes. The protocol states non human primates will be used for 12 - 24 months and either retired to a sanctuary, or euthanized if unable to be retired after final data collection. The inspectors were told that this animal would be euthanized later in the year (November). The claim that the animal was chaired for enrichment purpose was made by the attending veterinarian and investigator to the USDA inspection team.

The facility asks that "inflammatory" references be removed. Descriptive terms in the inspection report considered inflammatory were quoted directly from UCSF's animal medical records. It is common practice for inspectors to utilize the wording of the institution's records in inspection reports. Additional information found in the report came from discussions with the staff, including the attending veterinarian, and from direct observations of the animal.

During a May 29 reinspection, UCSF staff informed the inspector that they had euthanized animal V000335 subsequent the April inspection, and stated that the animal had been on study "too long." Additionally, UCSF staff stated that they should have stepped in and stopped the study prior to the April inspection. UCSF also stated that both animals cited on the inspection had been discussed with the IACUC at the next IACUC meeting following the inspection. However, the UCSF Compliance Manager then interrupted and stated that the condition of the second animal (MMU35184) was not discussed by the IACUC at that time, and as stated under issue # 2, page 8, had been brought to the attention of the IACUC.

Item II - Institutional Animal Care and Use Committee

-see paragraphs above

UCSF Staff also discussed the second animal (MMU35184) during the May 29th reinspection, stating that the word "severe" was never used in the medical record. The inspector and staff went through several pages of the record where the inspector pointed out the large number of entries and their tone, including one entry describing "violent masturbation" and other aberrant behavior. The attending veterinarian stated that he had only written the extensive notes in the records because of the unusual behavior exhibited by the animal.

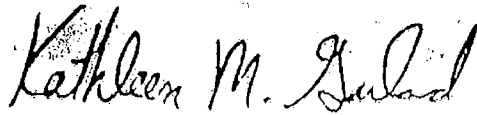
Item III- Defective caging

The nonhuman primate with the limb caught in the enclosure was identified by the institution and methods to correct and/or prevent the recurrence of limb entrapment were devised. However, UCSF failed to follow up and correct the problem. This type of non compliance has been cited at other institutions and resolved by cage alterations. The inspectors were not singling out the cage manufacturer, and at the time of inspection were

not even aware of the manufacturer's identity. Personnel at the facility acknowledged during the April inspection that the cage was defective.

Based on my review of the facts surrounding the inspection, I am not compelled to modify the inspection report. Thank you for your interest in the welfare of animals.

Sincerely,

A handwritten signature in cursive script that reads "Kathleen M. Garland".

Kathleen Garland, SACS
USDA, APHIS, Animal Care
Western Region

cc: Michael Smith, VMO