

Exhibit 16

7/28/15 OLAW letter to PPI



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
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

July 28, 2015

Re: Animal Welfare Assurance
#A4102-01 (OLAW Case F)

Mr. Paul Houghton
Chief Executive Officer and
Board Chair
Primate Products, Inc.
34200 Doctors Hammock Road
Immokalee, FL 34142

Dear Mr. Houghton,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 1, 2015 letter responding to my request for an assessment by the Primate Products, Inc. (PPI) Institutional Animal Care and Use Committee (IACUC) of allegations regarding serious and continuing noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy). According to the information provided, OLAW understands the following:

- 1) Two nonhuman primates cited in the allegations were supported by a PHS contract and the number of the contract was provided.
- 2) PPI notified OLAW that the USDA had identified potential programmatic issues of noncompliance.
- 3) a) Primate 0911132 was reported by a technician to exhibit a clinical indication of an exposed caudal vertebrae on 3/26/15. The veterinarian confirmed bone exposure on 3/30/15 and amputated the exposed tail tip on 4/1/15. Primate 3462110508 exhibited tail degloving on 1/12/15 and had the tail cleansed and ointment applied; partial tail amputation was conducted two days later and the animal was held in the intensive care unit until the case resolved. Primate 3994125505 was reported by a technician to exhibit tail degloving on 2/25/15 and was examined by the veterinarian who amputated the distal aspect of the tail on 2/27/15. The Institutional Animal Care and Use Committee (IACUC) determined that the cases were handled appropriately by the veterinary staff.

b) Animal care staff identified primate 1004072 to have a swollen middle finger on 10/5/15 and the digit was amputated on 10/6/15. The IACUC determined that prompt veterinary care had been provided.

c) Primate 06C009 was identified with a scrotal laceration and was under treatment and supportive care until its death on 3/14/15. An antibiotic resistant pulmonary infection was identified at necropsy. Primate F514 was identified to be losing weight on 9/1/14, was treated from 7/17/13 and died on 4/1/15. The IACUC determined that these animals could have been euthanized at an earlier time point but states that these decisions should be left to the discretion of the Attending Veterinarian.

- d) The veterinary staff informed the IACUC that quickly repositioning a rectal prolapse leads to quicker recovery and minimizes complications. The animal care staff was trained on the appropriate treatment for reducing a prolapse but instead held animals upside down and shook them which is not an accepted practice. The Attending Veterinarian informed the IACUC that not all prolapses require lubrication and suturing and can be manually reduced. Only veterinary staff or designees will now treat prolapses and all cases will be reported to the clinical veterinarian.
 - e) Teeth were extracted from a primate by an animal caretaker trained in the technique. Only veterinary staff or designees will now conduct dental procedures and this will be documented in the veterinary records. Tail amputations are performed only by veterinary staff and animals receive post-operative analgesics. This procedure will now be performed in the surgical suite.
 - f) Procedures such as suturing, amputations, debriding, and collecting CSF will now be performed in the holding building or clinic.
 - g) Psychological distress was not confirmed for primate A3E053 and animal 11168 was provided behavioral treatment. Primate A3E053 was provided behavioral treatment for picking at a tail wound. Primate A2E023 was provided with barriers during introduction into a group setting and was treated for injuries sustained from other primates in the enclosure. Primate 111618 received behavioral treatment.
 - h) Although the IACUC determined that daily health observations were made by veterinary and supervisory staff, the committee recommended that response to a presenting case be documented and that communication is improved between the husbandry and veterinary staff regarding responses.
 - i) The veterinary professional and technical staffing numbers are considered to be adequate.
- 4) a) It was confirmed that husbandry staff chase, restrain, and capture primates by the tail. The IACUC has directed the institution to stop this practice and a new standard operating procedure (SOP) was developed to address capture techniques.
- b) It was confirmed that nets containing one or more primates were dragged on the ground. Husbandry staff was counseled to carry the nets and not drag them. The new capture SOP states that the primary method of removing primates is from a chute and the secondary method is net capture.
 - c) The IACUC did not confirm that primates were chased around the enclosure for extended time periods for capture. Primates housed outside are trained to enter a chute and the transfer box or be sedated and removed.
 - d) It was confirmed that daily observation forms were not always submitted for all housing areas. The IACUC directed the husbandry supervisor or lead technician to submit observation forms daily, including for empty pens.
 - e) The IACUC did not confirm that there was a failure to report sick or injured primates.
 - f) Review of treatment and observation forms confirmed that some documentation was missing therefore it was not clear if all treatments had been given. The IACUC directed that following provision of treatment that the records are organized and filed by the Attending Veterinarian.

- g) Regarding wounding, rectal prolapses, tail degloving, and hair loss due to housing incompatible primates together, the IACUC did not substantiate this and determined the following: A2E023 was appropriately handled for injuries and received behavioral treatment; 3462110508 was treated for injuries and monitored while in a compatible social group; 1005158 was in a social group which received behavioral treatment for hair loss; M299 was treated for wounding and was in a social group which received behavioral treatment for aggression and hair loss; 1106013 was treated for a rectal prolapse and the social group received behavioral treatment for hair loss; 0908082 did not exhibit any of the issues stated in the allegation.
- h) The IACUC confirmed that primates may become wet during cage cleaning and therefore the cleaning SOP was revised to state that cover is to be provided to prevent wetting the primates. The IACUC confirmed that highly concentrated bleach solution had been used to clean cages and directed husbandry staff to use the correctly prepared bleach solution.
- i) The IACUC reviewed cleaning records and examined the reasons given for not completing cleaning of enclosures. If husbandry staff indicated that there was no time to clean the areas, they were counseled. The IACUC did not confirm that food and feces accumulated and led to mold growth.
- j) Primate 3908501726 was treated for a frostbitten, necrotic tail and for diarrhea. Heaters were not supplied to several groups of animals during low temperatures as per the SOP. The SOP was revised to stipulate that all outdoor housing areas will receive supplemental heat when temperatures are below 46F.
- 5) The IACUC confirmed that two primates were killed by a bear which breached the fence. The corrective action consisted of electrifying the fence.

Based on its assessment of these explanations, OLAW understands that some allegations were not substantiated while others were confirmed and corrective/preventive measures have been or will be taken. While this Office concurs with the actions taken to address the problems, we are concerned with the following:

- 1) There is an apparent lack of vigilance shown by the IACUC to identify problems and corrective solutions. Although the IACUC is not expected to direct the professional veterinary staff how to practice medicine, the committee is responsible for reviewing the program of veterinary care. It is concerning that the problems that were confirmed were not identified by husbandry, technical, or veterinary staff and promptly addressed by the IACUC and Attending Veterinarian. The expectation of Assured institutions is to self-identify and self-correct problems promptly and in an ongoing fashion. It is not clear whether the IACUC is using a checklist when conducting the semiannual program review and facility inspection or whether post-approval monitoring is occurring. Having the USDA or OLAW identify problems indicates an overall programmatic failure in oversight. Please provide additional information on the institutional and IACUC oversight of the program and how self-regulation is accomplished.
- 2) There is a failure to promptly report programmatic items of noncompliance to OLAW as agreed to in the Assurance signed by the Institutional Official and as outlined in PHS Policy IV.F.3. Please provide information on how the institution meets PHS Policy IV.F.3.

- 3) Indicate the job category of the individuals designated to conduct dental procedures and reduce rectal prolapses.
- 4) Indicate the number or percentage of primates that have been successfully trained to enter the chute for capture.
- 5) Please provide the two most recent semiannual program review and facility inspection reports.

Provide the requested information and any further updates on pending corrective actions by **August 17, 2015**.

Sincerely,



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

cc: IACUC Chair

Thomas J. Rowell, D.V.M., PPI President and COO

[REDACTED] NHP Resource Manager, NIH

[REDACTED] Contract Specialist, NIH

[REDACTED] Contract Specialist, NIH

Elizabeth Goldentyer, D.V.M., Eastern Regional Director, USDA-APHIS-AC

[REDACTED] (NIH/OD) [C]

From: [REDACTED] (NIH/OD) [C]
Sent: Tuesday, July 28, 2015 1:56 PM
To: [REDACTED]@primateproducts.com [REDACTED]@primateproducts.com'
Cc: [REDACTED]@primateproducts.com'; Betty.J.Goldentyer@aphis.usda.gov [REDACTED]
(NIH/OD) [E]; [REDACTED] (NIH/OD/ORS) [E]; [REDACTED] a (NIH/NIAID) [E]
Subject: OLAW A4102-F
Attachments: 1997_001.pdf

Good afternoon Mr. Houghton,

Attached please find Dr. Axel Wolff's response for OLAW A4102-01, Case-F.

If you have any questions, feel free to contact us by phone or by email.

Thank you,

[REDACTED]
*Project Analyst
Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Drive, Suite 360
Bethesda, MD 20892
301-594-[REDACTED]
[REDACTED]@od.nih.gov*