

**Exhibit 20**

**8/18/15 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

August 18, 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 August 12, 2015 letter responding to my July 28, 2015 request for information regarding allegations of serious and continuing noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Primate Products, Inc. (PPI) According to the information provided, OLAW understands the following:

- 3e) Procedures will now be performed in the surgical suite or holding building.
- 3g) Psychological distress was not noted in any of the three primates and OLAW's record reflects the correct number of the animal which was provided with behavioral treatment.
- 4h) As previously noted, the Institutional Animal Care and Use Committee (IACUC) confirmed that highly concentrated bleach solution had been used in one instance to clean cages. The IACUC addressed this issue, husbandry staff was retrained, and procedures regarding the use of bleach were modified.
  - 1) Institutional and IACUC oversight is accomplished by using the OLAW checklist when conducting the semiannual program review and facility inspection, reviewing new and existing standard operating procedures (SOP), reviewing/revising the Environmental Enhancement Program to Promote the Psychological Well-Being of Nonhuman Primates, reviewing protocols upon submission and annually, maintaining locked boxes on site for submission of anonymous animal welfare concerns, and utilizing an SOP which allows any employee to stop work if they feel that SOPs are not being followed or if human or animal health may be compromised.
  - 2) PPI has an SOP on prompt reporting to OLAW in compliance with PHS Policy IV.F.3.
  - 3) Veterinarians, veterinary technicians, and assistant technicians are the only individuals authorized to conduct dental procedures and to reduce rectal prolapses.
  - 4) The current animal population is 98% chute trained. New arrivals are in the process of being chute trained.

- 5) The October 2, 2014 facility inspection report and the April 21, 2015 program review were provided.

OLAW Comment: Both reports are noncompliant with the PHS Policy and OLAW guidance. There is no cover letter to the Institutional Official, no plans and schedules for correction, no responsible party listed to ensure correction, no interim status of the correction, and no completion date. Please review the enclosed sample documents and ensure that the next semiannual report is compliant with all of these requirements. Also, refer to OLAW guidance on our website to ensure that your overall program is compliant.

**Provide the October 2, 2014 program review and the April 21, 2015 facility inspection reports.**

- 6) SOPs were provided addressing cleaning and disinfecting of outdoor holding areas during quarantine and non-quarantine; hot and cold weather procedures; and the method of catching animals.

Based on its assessment of the information provided, its review of the supporting documents, and its evaluation of the information gathered during the site visit, OLAW has a better understanding of how PPI has addressed the noncompliant actions and how it currently manages the animal care and use program. Please address the following items:

- 1) Regarding prompt reporting to OLAW under PHS Policy IV.F.3:
  - A) Prompt reporting is applicable to all PHS-supported animal activities as well as all programmatic issues (whether PHS-supported or not). The intrusion of the bear constitutes a programmatic issue that should have been promptly reported.
  - B) SOP-112 3.4.13 describes euthanasia via CO<sub>2</sub>. This is clearly not applicable to the nonhuman primates. Please correct to reflect actual practices.
- 2) Provide a copy of the finalized and IACUC approved SOP addressing animal capture.
- 3) Provide the corrective plans developed in response to the findings of the August 11-13, 2015 USDA site visit.
- 4) Provide to the OLAW Division of Assurances an update on:
  - a) The training program including examples of topics, frequency, and which staff members attend. Also discuss other non-institutional training opportunities for staff and training for the IACUC members.
  - b) The change in veterinarian with program authority. Indicate that this has been changed from Dr. Rowell to [REDACTED] and provide her qualifications. Also, provide information on the backup veterinarian.
- 5) Confirm that when the heat lamps are in use, animals will be able to move freely in and out of chutes to prevent possible overheating and confirm that all of these lamps will only be powered by GFI outlets and that these outlets are available.

- 6) Provide an organizational chart showing all PPI staff ranging from the Institutional Official to the animal care and administrative staff. Show supervisory and reporting chains. Note that we were very impressed with the caliber and professionalism of the staff, many of whom have come on board since our last visit.
- 7) OLAW and USDA conducted an unannounced joint site visit on August 11, 2015 to assess the current state of the animal care and use program and to evaluate the corrective measures described in your written response. OLAW was pleased to see that a majority of the concerns had already been addressed and that efforts were underway to complete the remainder. During this visit additional changes to the animal care and use program were discussed and recommendations were made by the site visitors. Please provide an update on any of these as well as any other changes made to the animal care and use program.

Please provide the requested information by **September 21, 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

[REDACTED], Director DVR, NIH

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

**Memorandum to:**

**From:** Institutional Animal Care and Use Committee

**Subject:** Semiannual Report of the Program Review and Facility Inspection

**Date:**

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the Guide for the Care and Use of Laboratory Animals (Guide), and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

**Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.): [optional]**

**I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA**

Departures from the PHS Policy, the *Guide*, and the AWA.

Select A or B:

- A. There were no departures during this reporting period.
- B. The following departures have been reviewed and approved by the IACUC: [*include reason for each departure*]

**II. Deficiencies in the Institution's Animal Care and Use Program**

Animal Care and Use Program Review Date(s):

Select A or B:

- A. There were no deficiencies in the program during this reporting period.
- B. The following deficiencies have been identified: [*describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table*]

**III. Deficiencies in the Institution's Animal Facility**

Animal Facility Inspection Date(s):

Select A or B:

- A. There were no deficiencies in the animal facility during this reporting period.
- B. The following deficiencies have been identified: *[describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]*

**IV. Minority Views**

Select A or B:

- A. No minority views were submitted or expressed.
- B. The following minority views were expressed: *[insert minority views here or attach]*

**V. Status of AAALAC Accreditation** *[identify accredited facilities, if applicable]*

**VI. Signatures** *[signatures of a majority of the IACUC members required by AWAR (§2.31,c,3), if applicable]*

Names of IACUC Members	Signatures
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

**III. Semiannual Program Review and Facility Inspection Report**

Date:

Members in Attendance:

Deficiency Category*	✓	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete

- \* **A** = acceptable
- M** = minor deficiency
- S** = significant deficiency (is or may be a threat to animal health or safety)
- C** = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
- NA** = not applicable
- ✓ Check if repeat deficiency

#### IV. Endnotes

[i] The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

[ii] Part 2 Subpart C - Research Facilities  
 - 2.31(b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

[iii] 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

[iv] 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

[v] 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

[vi] 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

[vii] 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

[viii] 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

[ix] 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

[x] In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:  
 2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

2.31(d)(1)(iii) - "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

2.31(d)(1)(iv) - "Procedures that may cause more than momentary or slight pain or distress to the animals will:  
 - involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]  
 - not include paralytics without the use of anesthesia;"

2.31(d)(1)(x) - "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."

[xi] 2.33(a)(1) - "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]

[xii] 2.32(c) - "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."

[xiii] 2.32(c) - additional specifications include:  
 - "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"  
 - "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."  
 - "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].

[xiv] 2.31(d)(iv)(C) - "Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."

[xv] Part 3 Subpart A 3.8 - "...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition the plan must be approved by the attending veterinarian. The plan must provide written standard procedures..."