

**Exhibit 13**

**7/1/15 Response from PPI to OLAW**



**Primate Products, Inc.**

01 July 2015

Dr. Axel Wolf  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive MSC 7982  
Bethesda, MA 20892-7982

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

Dear Dr. Wolf:

Thank you for your query dated 5 June 2015. Please note attached response from the Primate Products Inc. (PPI) Animal Care and Use Committee who addressed the allegations and corrective actions that were taken when necessary. Please direct any questions or comments to Dr. Thomas J. Rowell (Institutional Official). He can be reached at [REDACTED] or email [REDACTED]@primateproducts.com.

PPI staff look forward to the feedback and appreciate this opportunity to respond. If I can be of any service directly please email me at [REDACTED]@primateproducts.com.

Sincerely,

Paul Houghton  
Chief Executive Officer

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Primate Products, Inc.

## MEMORANDUM

To: Thomas J. Rowell, Institutional Official

From: IACUC Committee

Date: 1 July 2015

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

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The Animal Care and Use Committee for Primate Products has reviewed OLAW's query and addressed the following combinations of allegations and questions listed below.

- 1) Indicate whether any of the allegations occurred with primates supported by a PHS/NIH grant or contract. If so, provide relevant grant and/or contract number.

*The IACUC concluded two animals are supported by HHSN272201400003I: 06C009 and A2E023 in which allegations were made.*

- 2) If noncompliance has occurred with any PHS-supported animals and/or was of a programmatic nature, indicate why the incidents was not promptly reported to OLAW. Programmatic problems include those associated with the program of veterinary care, training of technical/husbandry staff, husbandry program, overall physical plant issues, and IACUC related matters such as monitoring of the animal program.

*The IO alerted OLAW (email correspondence) on Tuesday 02 June 2015 as to potential programmatic issues of noncompliance as determined by the USDA and within 24 hours of receiving the completed report by USDA.*

- 3) Allegations of inadequate veterinary care consisting of:
  - a. Failing to promptly attend to primates with exposed caudal vertebrae (primate #0911132, 3462110508, 3994125505)

*The IACUC determined the following after a review of the records:*

- i. 0911132

*The first husbandry daily animal observation form recording "a bloody tail tip with white object sticking out" was Thursday, 3/26/15. The clinical veterinarian observed this animal on 3/26/15 and no treatment was instituted. On Sunday, 3/29/15 the husbandry daily observation form read "monkey with tail tip bone exposed". On Monday, 3/30/15, the husbandry daily observation form read "tail tip a little raw and has white object sticking*

*out of the bottom” veterinarian’s notes on this form indicate “Plan to amputate tomorrow morning. Bringing to ICU.”*

*The animal health record indicated that 1 cm of tail tip was amputated on 4/1/15, sutured and medication applied. No further findings recorded.*

*The same technician observed this animal 3/26/15 through 3/30/15, and there are inconsistencies in the observations reported. The first confirmation of bone exposure by a veterinarian is 3/30/15 and the tail was amputated 4/1/15. The IACUC confirmed, based on the information above, that there was adequate veterinary care, considering the outcome, but cannot conclude if it was prompt. The IACUC can only surmise that the clinical veterinarian didn’t think it warranted immediate attention.*

*This animal was redistributed and is no longer on site.*

ii. 3462110508

*The animal health record indicated that in response to the report of this animal’s tail being degloved, the tail was cleansed and an ointment applied on 1/12/15; then 2/3 of the tail was amputated two days later on 1/14/15. The animal was located in the ICU until 3/29/15. On 3/31/15, the case was reported as resolved.*

*The IACUC confirmed, based on the information above, that there was prompt veterinary care.*

*This animal was redistributed and is no longer on site.*

iii. 3994125505

*The husbandry daily observation form indicated on 2/25/15 that the animal had “degloved tail- raw”. The clinical veterinarian observed the animal on 2/25/15 and no treatment was instituted. The clinical veterinarian observed the animal again on 2/27/15, and the tail was amputated 5 cm. During the semi-annual preventative health exam on 3/19/15 no further tail abnormalities were indicated.*

*The IACUC confirmed, based on the information above, that there was prompt veterinary care.*

*This animal was redistributed and is no longer on site.*

b. Failing to promptly attend to primate with a fractured and exposed digit (#1004072).

*The first husbandry daily observation form reporting a “swollen finger middle finger” was dated 10/5/14. Veterinary response was “admitted to care on 10/6” as recorded on husbandry daily observation form. The animal health record indicated that on 10/6/15 the Left hand had D3 fractured with bone exposed and amputated D3 P1, P2 joint.*

*The IACUC confirmed, based on the information above, that there was prompt veterinary care.*

- c. Failing to promptly euthanize chronically ill, thin primates which later died (#06C009, F514).

i. 06C009

*After review of the history of this animal, the IACUC determined that this animal was a healthy male weighing 12.36 kg on 12/5/14, this male received a laceration to the left side of scrotum on 12/16/14, and was in declining health from then until this animal's death on 3/14/15.*

*During this time, the record demonstrated that the animal was examined often, treated extensively with medications and given additional nutrition and supplements, all in an attempt to reverse the animal's declining health as evidenced by diarrhea, dehydration and weight loss. None of the treatments had any lasting positive effect. Post mortem showed antibiotic resistant E-coli in lungs.*

*In hindsight, the IACUC concluded this animal could have been euthanized prior to 3/14/15.*

ii. F514

*A review of this animal's health record confirmed that this animal had a history of diarrhea, dehydration and weight fluctuation. The husbandry daily observation form of 9/1/14 reported this animal losing weight. The animal health record shows frequent examination, treatment and medication from 7/17/13 until this animal's death on 4/1/15.*

*Records indicated this animal did not adequately respond to treatment and failed to recover as intended.*

*In hindsight, the IACUC concluded, this animal could have been euthanized prior to 4/1/15.*

*In summary the IACUC concluded the animals (i.e. F514 and 06C009) listed above, received adequate veterinary care. Regarding euthanasia of sick animals; the IACUC concluded staff veterinarians use current approved veterinary practices to treat the animals and return them to healthy, comfortable living conditions. Additional attention could be given to evaluating the probability that a sick animal would be unlikely to survive and in the interest of animal welfare should be euthanized sooner rather than later; however, this decision should be left to the Attending Veterinarian.*

- d. Treating rectal prolapses by holding primate upside down and shaking them while repositioning the rectal mucosa. This procedure is sometimes performed outside, without anesthesia, lubrication, or suturing and without veterinary oversight.

*The IACUC determined that unexpected and sometimes sudden rectal prolapses occur in these species. Procedures documented in the literature for treating the conditions are summarized as follows:*

- *Apply gentle manual pressure distally to slide the distal end of the prolapse into the lumen and through the anal sphincter. The procedure may take several minutes.*
- *If mucosal edema makes reduction difficult, sucrose (table sugar) may be used as an osmotic agent to reduce the edema and make reduction easier. Anecdotally, the use of table salt has been described for the same purpose.*
- *If constipation is present, it should be aggressively treated.*
- *Unless gangrenous bowel is reduced and perforation results, no complications are expected. A small amount of bleeding may occur and is not a concern.*

*The veterinary staff reported to the IACUC that quickly repositioning the rectum helps the animal recover and minimizes complications. There is documentation of animal care staff being trained on these procedures. The practice of holding the animal upside down was not part of the training, and inconsistent with accepted practices.*

*The IACUC concluded, after discussions with the Attending Veterinarian that not all cases of rectal prolapse require correcting with anesthesia (e.g. some reduce on their own without any intervention) nor do they all consistently require suturing or lubrication. In addition moving forward only appropriately trained veterinary staff or designee will be able to initiate treatment.*

*In the future, the IACUC has recommended that all cases are reported to the clinical veterinarian for additional follow up.*

- e. *Pulling primate teeth by hand (by an animal caretaker) and amputating tail portions on unsanitized tables and without provisions of post-procedural analgesia or veterinary oversight.*

*The IACUC determined that the pulling of primate teeth by an animal caretaker has occurred however documentation was in place confirming the animal technician was trained on this procedure. Moving forward the IACUC has recommended that only the veterinary staff or designee will perform these procedures. The IACUC further recommended that this procedure is documented on the veterinary activity form (VAF), which is reviewed by the veterinarian and entered into the animal records.*

*The IACUC determined that tail amputations are performed by the veterinary staff exclusively and they are often assisted by the technicians. A review of the animal records for this procedure indicated that from September 2014 through May 2015, 11 of 12 animals received post procedure analgesics.*

*In the future, these cases will be transported to the clinic and be performed in the surgical suite, or the holding building, where conditions are better controlled.*

- f. *Performing veterinary procedures such as suturing, amputations, debriding, and collecting CSF in an outdoor area rather than in a dedicated, clean indoor space.*

*The IACUC determined that it was common practice to perform these procedures in an area of the outdoor animal housing areas, outside the animal cage that was designed to be*

*set up with portable examination tables where semiannual preventative health checks are performed.*

*The IACUC has recommended that these procedures occur indoors in the holding building or the clinic as determined by the Attending Veterinarian.*

- g. Failing to address cases of primates exhibiting clinical signs of psychological distress (#A3E053, A2E023, 111618)

*The IACUC determined the following after examining the animal health records and after consultation with the Head of Behavioral Sciences:*

*i.A3E053*

*The IACUC reviewed the animal's health record and there are no clinical signs of psychological distress.*

*This animal was redistributed and is no longer on site.*

*ii.A2E023*

*This animal arrived 11/07/14 with a wound on her tail, and was placed on behavioral treatment on 11/12/14 for picking at a wound on her tail. The IACUC concluded this behavior did not indicate psychological distress, but rather was secondary to her having a wound on her tail.*

*The animal was on this treatment until it was relocated to a social group outside on 01/15/15. Several animals in this group were noted with hair loss, so this entire group was provided with extra foraging opportunities 3X weekly. On 01/26/15, some aggression was observed in the group and floor barrels were added for extra visual barrier purposes.*

*On 02/06/15, hair loss in group was improving and this female was again observed picking at the wound on her tail; behavioral treatments continued. On 02/07/15, this animal was reported for a finger laceration. On 02/13/15, this animal was placed in a PANEL (a hurricane fence partition which allows the animal to remain in the social group, but only with partial contact to the social group) to allow the finger amputation to heal as well as to limit her movements to allow the tail wound to completely heal.*

*On 03/02/15, hair loss continued to improve and aggression was decreasing; behavioral treatments continued. On 04/01/15, her tail was noted as healed. The animal remained in the PANEL to make sure that the tail wound wouldn't reopen. On 04/24/15, aggression appeared to have decreased/resolved and group was noted as stable. Hair loss also continued to improve; behavioral treatments continued.*

*On 05/11/15, female was released from the PANEL, and tail was reinjured. Female was moved to ICU and tail was amputated.*

*The IACUC concluded the above detailed history does not imply that the original tail injury was due to psychological distress but rather the animal arrived with the injury. This injury continued to be an issue that was exacerbated by the animal indicating a chronic injury that ultimately resulted in the tail being amputated. Additionally, the animal was treated behaviorally for hair loss and the IACUC has deemed that this particular case of hair loss was not an indication of psychological distress.*

*iii. 111618*

*On 11/14/14 the husbandry daily observation form for Q9C was reported as OK – but an abnormal behavioral referral form (ABRF) was turned in to the behavioral department indicating that this animal was observed head tossing. This was the only documentation of a head toss until the semi-annual observation was performed.*

*This animal had a semi-annual behavioral observation on 1/27/15. It was noted this animal had hair loss and was observed head tossing. This animal was placed on behavioral treatment from 1/27/15 to 2/3/15, the animal was redistributed on 2/3/15.*

*The IACUC concluded the animal was not under psychological distress, and was appropriately treated for its behavioral observations.*

- h. Failure of veterinary and supervisory staff to respond to daily health observation reports.

*The IACUC determined that daily observation reports are reviewed and appropriately responded to. The clinical veterinarians prioritize cases, and there may be isolated incidents where delays in dealing with non-urgent observation reports are interpreted as failure to respond.*

*The IACUC has recommended revisions of daily observation recording and reporting procedures be implemented. There will be appropriate documentation of a response to any presenting case, and there will be better communication between animal care staff (i.e. people making the observation) and the veterinary staff regarding that follow-up.*

- i. Potential inadequate veterinary staffing for the numbers of primates housed.

*The IACUC concluded that three full time veterinarians as well as two veterinary technicians is adequate staffing for the number of animals currently on site.*

4) Allegations of inadequate husbandry practices consisting of:

- a. Chasing and capturing primates by the tail, removing primates from the cage fencing by pulling the tail.

*A subcommittee of the IACUC surveyed a representative sample of staff as to whether or not they have ever observed 1) chasing and capturing of primates by the tail, and 2) removing primates from the cage fencing by pulling the tail.*

*For 1) chasing and capturing of primates by the tail, 6 out of 6 surveyed stated that yes, they have observed this.*

*For 2) removing primates from the cage fencing by pulling the tail, 3 out of 6 surveyed stated that yes, they have observed this. 3 out of 6 surveyed stated no, they had not observed this.*

*The IACUC concluded that primates were not captured by their tails but were restrained and removed from the fence by grasping the animal on the back or by capturing in the net, to ensure safety of the staff member and no harm to the primate. The IACUC confirmed there have been no injuries to the animals that have resulted from this practice.*

*The IACUC has recommended that PPI employees no longer restrain nonhuman primates by the tail. This was initially done on 6/1/15, but was reiterated on 6/2/15, 6/4/15, and 6/18/15. Additionally, an interim plan has been initiated on 6/8/15, and a new SOP 254, is being developed to fully incorporate this change.*

b. Dragging capture nets containing one or more primates along the ground.

*A subcommittee of the IACUC surveyed a representative sample of staff as to whether or not they have ever observed 1) dragging capture nets containing one or more primates along the ground.*

*For 1) dragging capture nets containing one or more primates along the ground, 5 out of 6 surveyed stated yes, they have observed this. 1 out of 6 surveyed stated no, they have not observed this.*

*The IACUC concluded nets have been removed from a pen with one or more primates inside and instead of carrying the net, they were dragged on the floor. The IACUC confirmed there have been no injuries to the animals that have resulted from this practice.*

*The IACUC confirmed staff have been advised when using nets, carry the net, do not drag the net along the ground. This was initially done on 6/1/15, but was reiterated on 6/2/15, 6/4/15, and 6/18/15. Additionally a new SOP 254 is being developed indicating net catching as an alternative method rather than the primary method of capture in outdoor animal housing areas. The primary method will be removal of primates from the chute.*

c. Chasing primates for capture around the enclosure for extended time periods; there is no indication that the primates have been trained by positive reinforcement to enter transfer cage or other enclosures for stress free capture.

*A subcommittee of the IACUC surveyed a representative sample of staff as to whether or not they have ever observed 1) chasing primates for capture around the enclosure for extended time periods.*

*For 1) chasing primates for capture around the enclosure for extended time periods, 6 out of 6 surveyed stated no, they have not observed this however "extended time periods" was a relative phrase which may lead to subjective opinions.*

*The IACUC concluded animals were not chased around for extended time periods based on those questioned. If a specific animal was to be caught, that animal was caught immediately upon identification.*

*A new SOP 254 (however interim procedures are in place) is being developed indicating net catching as an alternative method rather than the primary method of capture in outdoor animal housing areas which eliminates the need to "chase" for capture. The primary method will be removal of primates from the chute. The IACUC has confirmed that upon being placed in an outdoor animal housing area at PTLC, all nonhuman primates are chute trained per SOP 242. SOP 242 is a training plan based upon operant conditioning techniques (including positive reinforcement) to train all animals to go into the chute on cue. Once in chute, it is possible to remove animals from the chute through use of transport boxes by placing the transport box in the chute. Additionally, animals can be squeezed in the chute for chemical restraint and removal.*

- d. Failing repeatedly to document daily observations of primates in the outdoor enclosures, including animals with health problems.

*A subcommittee of the IACUC interviewed the Operations Manager, Husbandry Supervisor, and President/Veterinarian regarding this question. 2 out of 3 stated no, they are unaware of this occurring, and 1 out of 3 stated yes, there are in fact dates where observations were not submitted. A review of the daily observations also demonstrated that there were days where observation forms were not submitted for some housing areas.*

*The IACUC confirmed observations for all animal housing areas are to be turned in no later than 10am each day. If an animal housing area does not currently have animals housed in it, "empty" is indicated on the form. The supervisor or lead technician designee will stamp the observation form with a time and date verifying all quads have been reported with an observation even if that observation is "all ok". This was initiated on 6/1/15.*

- e. Failing to submit prompt reports of sick and injured primates.

*A subcommittee of the IACUC interviewed the Operations Manager, Husbandry Supervisor, and President/Veterinarian regarding this question. 3 out of 3 stated that they are unaware of failure of staff to report sick and injured primates.*

- f. Failure of husbandry staff to administer veterinary prescribed treatments.

*A subcommittee of the IACUC interviewed the Operations Manager, Husbandry Supervisor, and President/Veterinarian regarding this question. 3 out of 3 stated no, they were not aware of this occurring. However, after reviewing documentation of the treatment and observation forms, there is in fact documentation missing indicating treatments may not have been instituted or simply the documentation is missing and treatments may have been instituted.*

*The IACUC established that it is the responsibility of vet staff or person designated by the veterinarian to institute treatments and all documentation is organized and filed by the Attending Veterinarian. Date instituted on 5/10/15.*

- g. Housing incompatible primates together for extended time periods resulting in wounding, rectal prolapses, tail degloving, and hair loss (#A2E023, 3462110508, 1005158, M299, 1106013, 0908082).

i. A2E023

*A subcommittee of the IACUC went through this animal's individual health record as well as corresponding reports. The review of this information does not indicate that this animal was housed with incompatible primates for an extended period of time resulting in wounding, rectal prolapses, tail degloving and hair loss. The animal arrived to the facility with a tail degloving wound on 11/7/14 at this time the animal was single housed for quarantine. On 11/11/14, during quarantine process, animal was noted with patchy hair loss lower legs. The animal was placed on behavioral treatment on 11/12/14 as this animal was also observed picking at this wound. On 11/25/14, during the second quarantine process, animal was noted with mild hair loss lower legs.*

*On 1/15/15 this animal was moved to a social group in [REDACTED] (NOTE: new social group was selected based upon behavioral and temperament evaluation of each animal). At this time, some aggression was noted and group was placed on the behavioral list for "Continue to Monitor (CTM)". Several animals in this group were noted with some hair loss (that occurred prior to group formation), and group was placed on behavioral treatment. On 1/26/15 aggression continued to be observed in this group and group was provided with floor barrels for extra visual barrier purposes. On 1/27/15 a hair loss assessment was done on this animal as 36% of body affected specifically patchy lower legs and arms, and behavioral treatment was continued. On 2/6/15, in [REDACTED] hair loss in group was improving and this female was again observed picking at the wound on her tail, behavioral treatments continued. On 2/7/15, in [REDACTED] this animal was reported for a finger laceration of left hand D2. Laceration was clipped, cleaned and sutured, and animal was returned to group. On 2/13/15, in [REDACTED] laceration had reopened with bone exposure, and D2 was amputated. This animal was placed in a PANEL in [REDACTED] to allow finger amputation to heal as well as to limit her movements to allow her chronic tail wound to completely heal. On 3/2/15, in PANEL in [REDACTED] hair loss continued to improve in group and aggression was decreasing, behavioral treatments continued. On 4/1/15, in PANEL in [REDACTED] tail had healed, animal remained in PANEL to make sure that the tail wound wouldn't reopen again. On 4/24/15, in PANEL in [REDACTED] aggression decreased/resolved and group was considered stable, hair loss also continued to improve, behavioral treatments continued. On 5/11/15, A2E023 was released from PANEL in [REDACTED] and during this monitored introduction the tail was reinjured. So animal was moved to ICU where the tail was amputated.*

*The IACUC concluded the above detailed history does not imply that the animals' original tail injury was due to being housed with incompatible primates. Rather the animal arrived with the injury, and this injury continued to be an issue that was exacerbated by the animal. This indicates a chronic injury that ultimately resulted in her tail being amputated. During the new group formation, aggression was noted and this animal received a minor injury to the left hand D2, but the animal was appropriately separated and provided partial contact with the group. Over time aggression decreased as the group hierarchy was established. In addition, the animal initially was reported with hair loss upon arrival at the facility, and this hair loss also improved over time including improvements while animal was socially housed.*

ii. 3462110508

*A subcommittee of the IACUC reviewed this animal's individual health record as well as corresponding reports. The review of this information does not indicate that this animal was housed with incompatible primates for an extended period of time resulting in wounding, rectal prolapses, tail degloving and hair loss. On 7/15/14, animal was placed in a new social group in [REDACTED]. On 8/28/14, in [REDACTED] this animal received a laceration to the left arm, was treated and returned to the group. On 1/12/15, this primate had a tail degloving injury, which resulted in the amputation of 2/3 of the tail. The animal was moved to ICU for treatment. On 3/31/15, tail was resolved and this animal was placed in a PANEL in [REDACTED] to be introduced to this new social group as the makeup of the original social group had changed. On 4/22/15, this animal was released from the PANEL in [REDACTED] to have full social contact with the rest of the animals. This animal was redistributed and is no longer on site.*

*The IACUC concluded the above detailed history does not indicate that this animal was housed with incompatible primates. The first wounding incident was minor, the second incident happened 4 months later, and after resolution, and the animal was introduced to the same location but with a different set of cohorts.*

iii. 1005158

*A subcommittee of the IACUC went through this animal's individual health record as well as corresponding reports. The review of this information does not indicate that this animal was housed with incompatible primates for an extended period of time resulting in wounding, rectal prolapses, tail degloving and hair loss. No reports of wounding, rectal prolapses or tail deglovings were found. On 4/8/14, while single housed, physical exam indicated thin hair over entire body. On 5/13/14, while single housed, observation noted as hair loss marked; generalized, continue to monitor. On 6/2/14, animal was moved to new social group in [REDACTED]. On 9/4/14, cohorts were redistributed and animal was moved to a new social group in [REDACTED]. On 11/14/14, the majority of group was noted with various forms of hair loss, and placed on behavioral treatment. This animal was also noted as submissive, continue to monitor. On 11/20/14, during semi-annual behavior observation, majority of the group was noted with hair loss, continued behavioral treatment. On 12/15/14, fighting was observed in the group, this animal was noted as submissive, and additional behavioral treatment was added. On 12/18/14, hair loss remained the same, behavioral treatment continued. On 1/27/15, aggression was decreasing and hair loss was improving, behavioral treatment continued. On 2/10/15, during semi-annual behavioral observation, majority of the animals were noted with hair loss, and behavioral treatment was continued. On 3/2/15, aggression was decreasing, hair loss was the same, and behavioral treatment continued. This animal was reported for submissive behavior, but it was determined by behavioral staff that the animal was a low ranking animal and intervention was not necessary. On 3/27/15, this animal was relocated to a new social group in [REDACTED] and introduced through a PANEL, as animals had shipped out and groups were being rearranged behaviorally. On 4/16/15, during semi-annual physical exam, animal was noted with hair loss. During the semi-annual physical, this entire group was relocated to [REDACTED].*

*On 5/5/15, animal was reported as self-plucking, behavioral staff did not observe this behavior, but hair loss remained in group and behavioral treatment continued. On 5/22/15, mild aggression within normal limits was observed in group, continue to monitor. On 5/27/15, hair loss was improving in group, behavioral treatment continued.*

*The IACUC concluded this animal had several reports of hair loss, but these were indicated both while the animal was single housed (3/26/14-6/2/14) and socially housed (in [REDACTED] 6/2/14-9/4/14; in [REDACTED] 9/4/14-3/27/15; in Q23D 3/27/15-4/16/15; and in [REDACTED] 4/16/15-present), which does not necessarily indicate being housed with incompatible primates as the cause of the hair loss.*

iv. M299

*A subcommittee of the IACUC went through this animal's individual health record as well as corresponding reports. The review of this information does not indicate that this animal was housed with incompatible primates for an extended period of time resulting in wounding, rectal prolapses, tail degloving and hair loss. No reports of rectal prolapses or tail degloving found. On 10/31/14, animal was noted with bite wounds on both forearms, treated and returned to group in [REDACTED]. On 11/3/14, animal presented with arm laceration, healing by second intention in Q15A. On 11/6/14, fighting in [REDACTED] was observed, and group was placed on behavioral treatment. On 11/27/14, wound on arm healing. On 12/18/14, aggression was decreasing, behavioral treatment continued. On 1/27/15, aggression was decreasing, behavioral treatment was stopped, but group was placed as continue to monitor on the behavioral list. On 2/12/15, during semi-annual behavioral observation, this animal, as well as others in group in [REDACTED] were noted with hair loss, and placed on behavioral treatment. On 2/27/15, wound on right arm dehisced, treated and returned to group. On 3/2/15, aggression was decreasing, continue to monitor. On 3/5/15, animal was placed in PANEL for closer observation of chronic wound on arm. On 3/10/15, hair loss increased in group, and behavioral treatment continued. On 3/18/15, during semi-annual physical exam, wound healed, and animal was released from PANEL into group, which had been relocated to [REDACTED]. On 4/24/15, aggression was decreasing and hair loss was improving in group, behavioral treatment continued. On 4/25/15, old chronic wound reopened, treated and returned to group. On 5/22/15, no fighting or aggression observed, hair loss improved, behavioral treatment continued.*

*The IACUC concluded the above detailed history does not indicate that this animal was housed with incompatible primates. A chronic wound in the same location on the body is not generally caused by other animals. Additionally, hair loss in this group improved over time with behavioral treatment. This treatment did not include removal of cohorts indicating that the cause of the hair loss is not incompatibility.*

v. 1106013

*A subcommittee of the IACUC went through this animal's individual health record as well as corresponding reports. The review of this information does not indicate that this animal was housed with incompatible primates for an extended period of time resulting in wounding, rectal prolapses, tail degloving and hair loss. No reports*

of wounding or tail deglovings were found. On 1/11/15 a husbandry observation form indicated a rectal prolapse for this animal in [REDACTED]. Husbandry indicated a visual check in morning and afternoon, both of which did not reveal a prolapse. On 1/22/15, the animal health record indicated a rectal prolapse that recurred two times in [REDACTED] was manually reduced and a purse string suture was performed, and animal was returned to group. Ketoprofen given for 2 days, once a day. On 2/6/15, during the semi-annual behavioral observation of [REDACTED] majority of the animals were noted with hair loss, and the group was placed on behavioral treatment. On 2-23-15, animal's rectal prolapse was rechecked and resolved. On 4/8/15, hair loss in group remained the same, behavioral treatment continued. On 5/21/15, hair loss in group was improving, behavioral treatment continued.

The IACUC concluded the above detailed history does not indicate that this animal was housed with incompatible primates. There are many reasons for a rectal prolapse including straining to defecate, diarrhea etc. This monkey has been in the same social group since 8/19/14, and these are the only indicated medical incidents up to date. The hair loss observed in this group improved over time with behavioral treatment. This treatment did not include removal of cohorts indicating that the cause of the hair loss is not incompatibility.

vi. 0908082

A subcommittee of the IACUC went through this animal's individual health record as well as corresponding reports. The review of this information does not indicate that this animal was housed with incompatible primates for an extended period of time resulting in wounding, rectal prolapses, tail degloving and hair loss. No reports of wounding, rectal prolapses, tail deglovings, or hair loss were found.

- h. Wetting primates while hosing out cages, using highly concentrated bleach solutions for cleaning of cages containing primates.

The Operations Manager, Husbandry Supervisor, and President/Veterinarian were interviewed regarding this question. 3 out of 3 stated yes, it has been possible for primates to get wet when the cage of an outdoor animal housing area is cleaned daily.

The IACUC confirms SOP 250 has been revised to provide cover for animals while in the chute when quads are being cleaned.

The Operations Manager, Husbandry Supervisor, and President/Veterinarian were interviewed regarding this question. 3 out of 3 stated yes, there was an incident that was reported on 4/21/15 to the IACUC regarding the suspected use of highly concentrated bleach solutions for cleaning cages. The IACUC investigated this incident, and promptly corrected the situation.

The IACUC confirmed bleach in the appropriate concentration has been made available for technicians to use eliminating the need for the technicians to individually dilute the bleach.

- i. Failing to clean enclosures daily resulting in accumulation feces and food and leading to mold accumulation.

All "Daily Quad Feeding and Cleaning Records" from September 1, 2014 to May 31, 2015 were reviewed. All days in the month of September and October were documented as "cleaning completed" for all outdoor animals housing areas. There were 6 quads that were not documented as "cleaning completed" in the month of November.

- 11-15-14, [REDACTED] reason=no water (tech JJ)
- 11-22-14, [REDACTED] reason=squeegeed due to broken pipe (tech JJ)
- 11-28-14, [REDACTED] reason=not flushing due to weather and holiday (tech MR)
- 11-28-14, [REDACTED] reason=not flushing due to weather and holiday (tech MR)
- 11-29-14, [REDACTED] reason=pump broke down (tech MR)
- 11-29-14, [REDACTED] reason=no water (tech JJ)

There were 5 quads that were not documented as "cleaning completed" in the month of December.

- 12-1-14, [REDACTED] reason=no time (tech JJ)
- 12-12-14, [REDACTED] reason=squeegeed, too cold (tech JJ)
- 12-13-14, [REDACTED] reason=not enough time (tech JJ)
- 12-15-14, [REDACTED] reason=not time (tech JJ)
- 12-17-14, [REDACTED] reason=no time (tech MR)

There were 4 quads that were not documented as "cleaning completed" in the month of January.

- 1-1-15, [REDACTED] reason=(no reason specified) (tech MR)
- 1-2-15, [REDACTED] reason=(no reason specified) (tech MR)
- 1-3-15, [REDACTED] reason=(no reason specified) (tech MR)
- 1-28-15, [REDACTED] reason=squeegeed (tech JJ)

There were 4 quads that were not documented as "cleaning completed" in the month of February.

- 2-14-15, [REDACTED] reason=squeegeed, raked around quad (tech JJ)
- 2-14-15, [REDACTED] reason=squeegeed, raked around quad (tech JJ)
- 2-14-15, [REDACTED] reason=squeegeed, raked around quad (tech JJ)
- 2-19-15, [REDACTED] reason=(no reason specified) (tech AR)

There were 13 quads that were not documented as "cleaning completed" in the month of March.

- 3-1-15, [REDACTED] reason=squeegeed, water pipe to hose broken (tech JJ)
- 3-3-15, [REDACTED] reason=squeegee and pools due to broken pipe (tech MR)
- 3-3-15, [REDACTED] reason= squeegee and pools due to broken pipe (tech MR)
- 3-3-15, [REDACTED] reason= squeegee and pools due to broken pipe (tech MR)
- 3-3-15, [REDACTED] reason= squeegee and pools due to broken pipe (tech MR)
- 3-3-15, [REDACTED] reason= squeegee and pools due to broken pipe (tech MR)
- 3-3-15, [REDACTED] reason=squeegeed (tech JJ)
- 3-4-15, [REDACTED] reason=squeegee and pools due to broken pipe (tech AR)
- 3-4-15, [REDACTED] reason= squeegee and pools due to broken pipe (tech MR)
- 3-4-15, [REDACTED] reason= squeegee and pools due to broken pipe (tech MR)
- 3-4-15, [REDACTED] reason= squeegee and pools due to broken pipe (tech MR)
- 3-4-15, [REDACTED] reason= squeegee and pools due to broken pipe (tech MR)
- 3-4-15, [REDACTED] reason=squeegeed (tech JJ)

All days in the month of April and May were documented as "cleaning completed" for all outdoor animals housing areas. On any day listed above that indicated "no time" as the

*reason for not cleaning an outdoor animal housing area, there is documentation that the Operations Manager counseled the technicians as this was deemed an inappropriate response.*

*The IACUC concluded there were isolated days in which the outdoor animal housing areas were not flushed, but squeegeed, so this never resulted in an accumulation of food and feces leading to mold accumulation.*

- j. *Failing to provide supplemental heat to primates housed outdoors during cold weather for numerous days; this failure may have led to frostbite and necrosis of the tail (#3908501720) as well as possible mortality.*

*The IACUC determined there has never been an animal on our site with the ID 3908501720. There is an animal with the ID of 3908501726 that was onsite, so this may be the animal that this allegation is referring to. If so, according to the animal health record of 3908501726, this animal was housed outside (Q25C), but moved inside to a single cage (HB1/108/12) on 11/29/14 due to an observation of “dehydrated; thin”, response was “placed on treatment(s)”, there were also comments listed in this observation “oral rehydration food supplements house singly indoors. Frostbitten tail tip (4 cm) may need tail dock in 2-3 days”. The animal was placed on treatment of Gatorade and food supplements SID until 12/3/14. On 12/4/14, there was an observation of “necrotic, frost bitten tail”, response was “placed on treatment(s)” there were also comments listed in this observation “loose stool, dehydrate, IV fluid tx, abx antidiarrheal, tail docked 4/5 of tail, vitamin B comp/iron supplements, pain meds”. The animal was placed on treatment of tylosin inj. IM SID until 12/10/14, LRS IV SID until 12/7/14, bismuth subsalicylate PO SID until 12/8/14, vitamin B complex IM EOD until 12/8/14, and ketoprofen IM SID until 12/6/14. On 12/6/14, there was observation of “dehydrated; thin”, and response was “continue treatment”. On 1/8/15, there was an observation of “rechecked hydration”, and response was “resolved”, and an observation of “recheck stool”, and response was “resolved”. This animal was redistributed and is no longer on site.*

*Additionally, temperatures were pulled for the following days (from [www.weatherunderground.com](http://www.weatherunderground.com)):*

- 11-29-15: mean 60F, high 77F, low 42F*
- 11-28-15: mean 54F, high 69F, low 39F*
- 11-27-15: mean 57F, high 75F, low 39F*
- 11-26-15: mean 62F, high 77F, low 46F*
- 11-25-15: mean 82F, high 89F, low 75F*

*According to SOP 221, when temperatures fall or are predicted to fall below 46F a wind break is required to be in place, animals are not to be locked in the chutes, barrels may be supplied for more shelter for larger groups, and heat lamps and propane heaters may also be used as appropriate. Additionally, no outdoor animal housing areas will be washed down while the temperature is below 50F, instead they will be squeegeed and spot cleaned [redacted] (where this animal was located) did have the wind break up, but heaters were not supplied to this group on the above dates.*

*A review of SOP 221 by the IACUC indicated that not all outdoor housing areas are provided supplemental heat if the temperature falls or is predicted to fall below 46F. The IACUC confirmed SOP 221 will be revised to indicate that all outdoor animal housing areas will be provided with supplemental heat when the temperature falls or is predicted to fall below 46F.*

5) Allegations of inadequate secondary containment.

- a. Failing to provide a secure perimeter fence which resulted in a bear entering the animal facility and killing two primates.

*The IACUC determined Class II Florida Fish and Wildlife permits require fencing around the perimeter of enclosures holding permitted animals; the fencing is required to keep the permitted animals within the perimeter. The Guide states that successful management of outdoor housing relies on consideration of adequate security via a perimeter fence or other means. In 2001 PPI built a 72 inch 9 gauge fence with a 12 inch topping of barbed wire to create a perimeter around the Centiquad housing and holding building at Panther Tracks. From the date the fence was raised in 2001 until October 2014 there were no known predator entries into the enclosed compound.*

*In October 2014 a Florida black bear was spotted in the early morning hours in the compound and had gained entry by bending in a portion of fence. The fence was repaired at the damaged spot. The Director of Facilities contacted Florida Fish and Wildlife to make them aware that there was a nuisance bear present on the property in the area where animals were being held attempting to get access to animal feed. The Biologist with the office recommended electrifying the fence to deter the bear. The bear gained entry into the perimeter a second time (the next day) and caused the deaths of two nonhuman primates. The fence was electrified within 48 hours.*

*The electric for the fence is run by solar power and activated at the end of the work day; lights flashing on the wire indicate the current is running. The IACUC determined there has not been an incident with the bear since the fence was electrified.*

**Wolff, Axel (NIH/OD) [E]**

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**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Monday, July 06, 2015 7:28 AM  
**To:** 'Thomas Rowell'  
**Subject:** RE: Animal Welfare Assurance # A4102-01 (OLAW Case F)

Thank you for this report, Dr. Rowell. As you may know, cases are handled in the order received so I will respond accordingly.

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

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**From:** Thomas Rowell [mailto: [REDACTED]@primateproducts.com]  
**Sent:** Wednesday, July 01, 2015 2:54 PM  
**To:** Wolff, Axel (NIH/OD) [E]  
**Cc:** Paul Houghton  
**Subject:** Animal Welfare Assurance # A4102-01 (OLAW Case F)

Dear Dr. Wolf,

Paul Houghton asked that I forward the attached letter and the response from PPI's Animal Care and Use Committee (signed copy by the ACUC on site) which addresses the allegations and questions in your letter dated 05 June 2015. Please contact me if I can provide additional information. I can be reached at [REDACTED]

Sincerely,

Jeff

PS. I ask that you distribute the response as you deem appropriate.

Thomas J. Rowell, DVM  
President/Chief Operating Officer  
**Primate Products, Inc.**  
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