DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

August 27, 2019

Re: Animal Welfare Assurance
#A3645-01 (OLAW Case 1C)

Dr. Greg Westergaard
President and CEO
Alpha Genesis, Inc.
95 Castle Hall Road, PO Box 557
Yemassee, South Carolina 29945

Dear Dr. Westergaard,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 26, 2019 letter responding to our request for additional information regarding your report dated August 15, 2019. Based on your response to our questions we understand that the reason for the delay in checking the lixits was due to falsification of records by the technicians on duty. We further understand that employees are trained regarding this issue (checking drinking-water systems) and have since been re-trained on these procedures. We also understand that staffing levels are adequate and that there was no staffing shortage at the time of the incident.

We thank Alpha Genesis for promptly addressing each of the individual questions and providing answers. We appreciate your cooperation as Institutional Official regarding this unfortunate matter in particular and find no cause for further action by this office at this time. Please continue to report to this office immediately any further incidents regarding lack of water supply to animals or failure of staff to check watering systems as required.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact
Dr. Robert M. Gibbens, USDA, APHIS, AC

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AlphaGenesis INCORPORATED

AlphaGenesisInc.com
866.789.MONK (6665)
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95 Castle Hall Road
Yemassee, SC 29945

Primates
Research
Housing
Bio Products

August 26, 2019

RE: Animal Welfare Assurance

#A3645-01(OLAW Case 1C)

Dr. Brent Morse, Division of Compliance Oversight

Office of Laboratory Animal Welfare

National Institute of Health

6705 Rockledge Drive

RKL 1, Suite 360, MSC 7982

Bethesda, MD 20892-7982

Dear Dr. Morse,

Please see below as per additional requested information:

Q1: Why was no further action apparently taken to immediately check the watering system after the events on August 10th?

A1: The technicians on duty documented that they had checked the lixits each day and that the lixits were in working order. Management determined that the lixit checks were not done correctly, and immediately terminated the two employees who were most directly responsible.

Q2: Are all employees aware that this was an emergency situation, especially considering the seasonal conditions, requiring immediate resolution and notification of veterinary and management personnel?

A2: Yes, employees are trained on this issue, and on the proper procedures for responding and reporting to supervisory staff. Staff have since been re-trained on these procedures. Please note that the animal area in question was in a temperature controlled indoor environment not subject to seasonal conditions.

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Q3: Is the staffing level adequate such that it is practical for all lixits to be triple-checked on a daily basis?

A3: Yes, staffing levels were adequate.

Q4: Was there a staffing shortage during this time?

A4: No, there was not a staffing shortage.

Please feel free to contact me with additional questions or concerns.

Sincerely,

(b) (6)

Dr. Greg Westergaard

Institutional Official

Alpha Genesis Inc

gwprimate@alphagenesisinc.com

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Morse, Brent (NIH/OD) [E]

From: Ward, Joan (NIH/OD) [E]
Sent: Monday, August 26, 2019 11:10 AM
To: Morse, Brent (NIH/OD) [E]
Subject: FW: OLAW Case A3645-1C
Attachments: OLAW response 8.26.2019.pdf

FYI
From: Kim Schmidt <drkim@alphagenesisinc.com>
Sent: Monday, August 26, 2019 11:03 AM
To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Cc: gwprimate@alphagenesisinc.com; (b) (6) Gibbens, Robert - APHIS (Robert.M.Gibbens@aphis.usda.gov) <Robert.M.Gibbens@aphis.usda.gov>
Subject: Re: OLAW Case A3645-1C

Thank you Ms. Ward.

Please find the response attached.

Kim Schmidt

On Thu, Aug 22, 2019 at 11:07 AM Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov> wrote:

> Dear Dr. Westergaard,
>
> Attached please find Dr. Brent Morse's initial response to OLAW Case A3645-1C.
>
> If you have any questions, feel free to contact us by phone or by e-mail.
>
> Regards,
>
> Joan
>
> *Joan Ward*
>
> *Program Specialist*
>
> *Office of Laboratory Animal Welfare*
>
> *National Institutes of Health*

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6700B Rockledge Dr., Suite 2500

Bethesda, MD 20892

301-496-7163

wardjoa@od.nih.gov

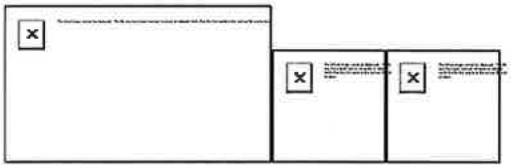
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Kimberly Schmidt, DVM

Attending Veterinarian

(b) (6)

www.AlphaGenesisInc.com





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August 22, 2019

Re: Animal Welfare Assurance
#A3645-01 (OLAW Case 1C)

Dr. Greg Westergaard
President and CEO
Alpha Genesis, Inc.
95 Castle Hall Road, PO Box 557
Yemassee, South Carolina 29945

Dear Dr. Westergaard,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 15, 2019 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Alpha Genesis, Inc. (AGI). From the information provided OLAW understands that on August 10, 2019 two rhesus macaques were found dead and another was found dehydrated. That animal was treated for dehydration and suspected diarrhea and is recovering. Two days later another rhesus was found dehydrated and treated but subsequently died. At that time an investigation of the animals' housing was performed finding the water supply to the caging was not functioning properly. The affected animals were supported by PHS-funded contracts to AGI. It is understood that the funding components have been notified.

Although AGI has a three-tier system in place to check water lixits are functional on a daily basis, personnel responsible for these checks did not perform this job function in this circumstance. A veterinary technician and the supervisor responsible for the lixit checks have been terminated. The supervisor and manager involved in training those involved and ensuring technicians are adequately performing their duties have received disciplinary actions and conditional continued employment. AGI is in the process of hiring an additional animal care manager. AGI's QA officer will verify that the described procedures are being performed adequately on a monthly basis, and managers and supervisors will report daily to the Director or Attending Veterinarian all lixits have been checked.

OLAW believes that the corrective and preventive measures by Alpha Genesis, Inc. are appropriate and consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring, self-correction and self-reporting. We appreciate being informed of this matter and **we request further information:** please provide an explanation or further information regarding the interval between August 10 and August 12. Why was no action apparently taken to immediately check the watering system after the events on August 10th? Are all employees aware that this was an emergency situation, especially considering the seasonal conditions, requiring immediate resolution and notification of veterinary and management personnel? Is the staffing level adequate such that it is practicable for all lixits to be triple-checked on a daily basis? Was there a temporary staffing shortage during this time? Please provide this information to our office **by September 5, 2019**.

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Sincerely,

(b) (6)

Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact
Dr. Robert M. Gibbens, USDA, APHIS, AC

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A3645-1C

AlphaGenesis INCORPORATED
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866.789.MONK (6665)
Fax 843.589.5290
95 Castle Hall Road
Yemassee, SC 29945

Primates
Research
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August 15, 2019

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institute of Health
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, MD 20892-7982

Dear Director,

This self-report describes an incident that was discovered on 8/12/2019 at Alpha Genesis Incorporated (AGI). The contract numbers that supported the animals involved are HHSN272201000051C (Animal ID L558) and HHSN263201600011I (Animal IDs H21V, DX58, BR7F). The funding components have been notified. The Alpha Genesis, Inc. assurance number is D16-00387 (A3645-01).

On 8/10/2019, two *Macaca mulatta* H21V and DX58 were found dead and one BR7F was found dehydrated. The dehydrated animal was brought to clinic and treatment initiated for dehydration and suspected diarrhea. On 8/12/2019 an additional *Macaca mulatta* L558 was found dehydrated and brought to clinic for treatment. At this time an investigation of the animals' housing was performed finding the water supply to the caging was not functioning properly. L558 died during treatment on 8/14/2019 and BR7F is recovering with continued treatment.

AGI has a three-tier system in place to check water lixits are functional on a daily basis. An animal care supervisor, animal care technician and veterinary technician are all required to check every single lixit every single day. In addition, any disruptions in water lines involving repair or disconnection, or in any situations where an animal moves into a cage that was previously unoccupied, are required to be documented with paperwork and inspected by a supervisor or manager. This system has been designed to provide redundancy in safety checks involving water lines and has been extremely effective since it was initiated. However, in this circumstance, the supervisor, the animal care technician and the veterinary care technician from 8/9/2019-8/11/2019 did not perform one of their main job functions of checking the lixits. The veterinary technician and the supervisor responsible for the lixit checks have been terminated. The supervisor and manager involved in training those involved and ensuring technicians are adequately performing their duties have received disciplinary actions of an unpaid two week suspension and conditional continued employment. AGI is also in the process of hiring an additional animal care manager. Procedures will continue as described above, AGI's QA officer will verify these procedures are being performed adequately on a monthly basis, and managers and supervisors will report daily to the Director or Attending Veterinarian all lixits have been checked. We deeply regret this incident and require every employee to take their job duties seriously and perform them according to established SOP. It is an honor and a privilege to care for these animals and all employees must adhere to providing the highest level of care.

Respectfully submitted,

(b) (6)

Dr. Greg Westergaard
Institutional Official
Alpha Genesis Inc
gwprimate@alphagenesisinc.com

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 19, 2019 7:25 AM
To: Kim Schmidt
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: self report from AGI D16-00387 (A3645-01)

Thank you for this report, Dr. Schmidt. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Kim Schmidt <drkim@alphagenesisinc.com>
Sent: Friday, August 16, 2019 11:46 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: self report from AGI D16-00387 (A3645-01)

Please find attached.

--

Kimberly Schmidt, DVM

Attending Veterinarian

(b) (6)

www.AlphaGenesisInc.com



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