From: Ward, Joan (NIH/OD) [E]
To: mbroadhurst@altasciences.com

Cc: (b) (6) Gibbens, Robert - APHIS

Subject: OLAW Case A4261-O

Date: Wednesday, June 12, 2019 8:44:14 AM

Attachments: 2829 001.pdf

Dear Mr. Broadhurst,

Attached please find Dr. Brent Morse's final response to OLAW Case A4261-O.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards, Joan

Joan Ward
Program Specialist
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National Institutes of Health
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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

June 10, 2019

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

Re: Animal Welfare Assurance #A4261-01 (OLAW Case O)

Mr. Mike Broadhurst General Manager and Institutional Official Altasciences Preclinical Seattle, LLC (formerly SNBL USA) 6605 Merrill Creek Parkway Everett, WA 98203

Dear Mr. Broadhurst,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 30, 2019 letter and attachment containing the report of an adverse event within your animal care and use program that occurred on April 8, 2019. According to the information provided, OLAW understands that an approximately 9.3kg Gottingen minipig died of circulatory failure resulting from cardiac tamponade during a thoracic inlet blood collection procedure. Although the procedure was performed by two experienced technicians, multiple unsuccessful needle insertions were attempted. Necropsy results did not indicate trauma to any tissue or blood vessel in the thoracic inlet region. This animal was supported by PHS (BARDA) funds.

Corrective and preventive actions included the PI immediately suspending blood collection from the thoracic inlet. Blood collections are now collected from a peripheral vein unless it's a terminal collection. The applicable SOP will be updated to: further define and limit the number of blood collection attempts; limit the collection site to the right side of the animal unless it is a terminal collection, and; draw from the cranial vena cava only when necessary or the volume of blood requires collection from the cranial vena cava. The Time Out campaign will be discussed with staff and the acclimation training requirements for swine prior to a thoracic inlet blood collection will be reviewed and revised.

The prompt consideration of this matter by Altasciences was consistent with the philosophy of institutional self-monitoring, self-reporting and self-correction. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b)(6)

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

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

Bai Nguyen (OS/BARDA)