



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 22, 2018

Re: Animal Welfare Assurance  
A4234-01 [OLAW Case D]

Ms. Kristina Guberski  
Director of Quality and Compliance  
Biomere  
57 Union Street  
Worcester, MA 01608

Dear Ms. Guberski,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 21, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Biomere, following up on an initial telephone report on August 17, 2018. According to the information provided, OLAW understands that nine mice died because they had not been monitored following a procedure and recovery from anesthesia. The veterinarian was not called and the Institutional Standard Operating Procedures regarding post-procedural monitoring had not been followed.

The corrective actions consisted of retraining the individual responsible, developing an animal recovery and monitoring form, and training all staff on these procedures.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair



57 Union Street, Worcester, MA 01608  
508 459 7544 biomere.com

File No. D16-00632 (A4234-01)

August 21, 2018

Director, Office of Laboratory Animal Welfare  
Office of Extramural Research,  
Office of the Director, National Institutes of Health  
RKL 1, Suite 360  
6705 Rockledge Dr.  
Bethesda, MD 20892-7982

**RE: Assurance number: D16-00632 (A4234-01). Prompt Reporting**

Dear Director, Office of Laboratory Animal Welfare:

This letter is a follow-up of the preliminary report regarding failure to monitor animals post-procedurally as necessary to ensure well-being during recovery from anesthesia.

This event occurred during a study for the comparison of the immunogenicity and vaccine efficacy of several different HSV-2 gD-2 liposome vaccine prototypes. The first seven groups were initially and successfully administered intranasal test article and sampled for blood and vaginal secretions. In the subsequent five groups a total of nine mice were found dead. The same anesthetic dose was administered to all mice and it is not believed there is any toxicity due to the test articles, similar formulations of which have been dosed many times before without adverse effect.

It was determined animals were not monitored post-procedurally as described in internal Standard Operating Procedures. Appropriate post-procedural monitoring would have allowed for the veterinarian to be contacted immediately. This was an isolated incident and the individual involved will attend a specialized retraining. Corrective actions also include implementing an Animal Recovery and Monitoring Form and group retraining to prevent future incidents.

Sincerely,

(b) (6)

Kristina Guberski, B.S.  
Institutional Official  
Director of Quality and Compliance  
Biomere

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## Initial Report of Noncompliance

By: aw

Date: 8/17/18

Time: 1:30

Name of Person reporting: Kristina Guberski

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Biomeve

Assurance number: A4234

Did incident involve PHS funded activity? Yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Vaccine study, 9 mice died, not monitored as per policy, not called & mice not euthanized

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Retrain staff; Counsel all investigators

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_