

From: [Gibbens, Robert - APHIS](#)
To: [Garland, Kathleen M - APHIS](#); [Keller, Martha - APHIS](#)
Subject: FW: OLAW Case A3368-E
Date: Monday, May 11, 2020 9:49:00 AM
Attachments: [0218_001.pdf](#)

FYI

From: Walker, Keri (NIH/OD) [C] [mailto:keri.walker@nih.gov]
Sent: Monday, May 11, 2020 7:44 AM
To: TomSpalding@PacificBioLabs.com
Cc: (b) (6) Gibbens, Robert - APHIS <robert.m.gibbens@usda.gov>
Subject: OLAW Case A3368-E

Dear Mr. Spalding,

Attached please find Dr. Tubbs' final response to OLAW Case A3368-E.

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

Best Regards,
Keri

*Keri Walker
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR US POSTAL SERVICE DELIVERY:

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May 1, 2020

Re: Animal Welfare Assurance
A3363-01 [OLAW Case E]

Mr. Thomas L. Spalding
President
Pacific BioLabs
551 Linus Pauling Drive
Hercules, CA 94547

Dear Mr. Spalding,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 31, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Pacific BioLabs following up on the preliminary report dated March 24, 2020.

According to the information provided, this Office understands that the Pacific BioLabs Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: two studies that were initiated (March 15, 2020) prior to the expiration of an Animal Care and Use Protocol (ACUP) which involved intracutaneous test in rabbits dated March 16, 2020. The studies were conducted past the expiration date and ended on March 19, 2020. The final report states an investigation was conducted by the IACUC Chair and Attending Veterinarian. It was determined that the principal investigator (PI) overlooked the expiration date of the protocol while managing multiple studies and dealing with reduction in resources due to COVID-19. Also, the PI was waiting for potential updated documents from ISO to include in the ACUP renewal. The report states it was a combination of these factors that led to the oversight. Corrective actions included the following:

- Toxicology Management counseled the involved employee and reiterated the importance of assuring animals are only assigned to active, IACUC approved ACUPs.
- Toxicology Management has instructed Quality Assurance to provide timely reminders for ACUP renewals.
- ACUP compliance and renewals will now fall to the responsibility of the Toxicology Director.
- The Director will work closely with the IACUC to devise a centralized, on-line management system and tracking for all ACUPs, and to ensure this oversight will not be repeated.

It is noted that the final report did not include the funding source involving the incident. In the future, please include the source of funding and provide grant numbers for all PHS or NSF supported work. Based on its assessment of this explanation, OLAW understands that the Pacific BioLabs has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact
Robert M. Gibbens, DVM, Director, Animal Welfare Operations