ANIMAL WELFARE COMPLAINT

Complaint No.	Date Entered:	Processed By:
AC22-160	December 23, 2021	Robert Baxter

Referred To:	Reply Due:
Tonya Hadjis	January 22, 2022

Facility or Person Complaint Filed Against

Name:	Customer No.:	License No.:
Product Safety Labs	44516	

Address:	Email Address:
2394 US Highway 130	

City:	State:	Phone No.:
Dayton	NJ	(732) 438-5100

Complainant Information

Name:	Organization:
(b) (6), (b) (7)(C), (b) (7)(D)	[redacted]

Address:	Email Address:
(b) (6), (b) (7)(C), (b) (7)(D)	(b) (6), (b) (7)(C), (b) (7)(D)

City:	State:	Phone No.:
[redacted]	[redacted]	(b) (6), (b) (7)(C), (b) (7)(D)

How was the Complaint received?
Email

Details of Complaint:
See attached.

Results:
This complaint refers to citations on a prior inspection report.

Animal Care inspectors conduct unannounced inspections for all USDA registered and licensed facilities. Our authority is to ensure that they meet the standards required by Federal regulations. Inspectors also perform inspections in response to valid concerns and complaints received from the public to ensure the well-being of the animals and compliance with Federal law.

When non-compliant items are found, these non-compliances are cited on the inspection report under the most accurate regulation based on the circumstances of the issue. Multiple non-compliances for the same issue are only cited when appropriate. With the exception of focused inspections, inspectors evaluate the facility for compliance with all applicable regulations. Although all regulatory requirements are assessed, only non-compliant items are listed on the inspection report.

Animal Care will continue to inspect this facility to ensure that past non-compliances are corrected and that AWA-regulated animals are protected to the fullest extent of Federal law.

Application Kit Provided:
Yes: No:

Inspector: JESSICA GOWINS	Date: January 6, 2022
Reviewed By: Tonya Hadjis	Date: July 13, 2022

From: [redacted]
To: Gibbens, Robert - APHIS; APHIS-AnimalCare
Subject: [External Email]Product Safety Labs -- Federal Complaint
Date: Tuesday, November 30, 2021 11:56:30 AM

Dr. Robert Gibbens 12/1/21
Director, Animal Welfare Operations, USDA/APHIS/AC,
2150 Center Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117

Dr. Gibbens,

I am writing to you today to file an Official Complaint against Product Safety Labs (22-R-0143)
for clear violations of the Animal Welfare Act regarding the deaths of three rabbits due to inexcusable negligence by lab staff.

As you know, the facility was inspected 10/26/21, and the report cites this lab, and its bungling staff:

"2.31(d)(1)(viii) Institutional Animal Care and Use Committee (IACUC) . . . 3 rabbits were used in a skin irritation study. The scientist assigned to prepare the test article did not dilute it as prescribed protocol's special instructions. The test article should have had 1:64 dilution. The solution was applied to the rabbit's skin and the skin was wrapped at 10:49AM as prescribed in the protocol. During a skin check at 3:37PM, the animal care technician noted signs of edema and erythema. At 4:05PM the rabbits were provided with analgesics. Twenty-four hours after the application of the solution the rabbits were euthanized due to levels of edema and erythema of the skin."

This botched procedure led directly to the deaths of these rabbits, and caused them significant pain, as evidenced by the ***"edema and erythema of the skin."***

This entire incident was entirely avoidable, and was caused by the error of the clearly unqualified personnel at this facility. Therefore, this incident would also violate: ***Sec. 2.32 Personnel qualifications. (a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.***

This incident also violated: ***Sec. 2.38 Misc. (f)(1) Animal Handling of the Animal Welfare Act which states: "Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort."***

Clearly these animals were not handled in a way which would not cause pain or physical harm.

As you know, ***Sec. 2.36 Annual report (7)*** requires that the research facility annual report must:
"State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report;"

As you can see from the attached annual report, Product Safety Labs (22-R-0143) not only caused the death of these animals, but also failed to report that these rabbits experienced any pain, essentially lying about the suffering that their negligence caused.

Since Product Safety Labs (22-R-0143) negligence has caused severe animal suffering and multiple deaths, I must insist that you take the most severe action allowable under the Animal Welfare Act and immediately launch a full investigation and at the conclusion of the investigation issue the maximum fine allowable against Product Safety Labs (22-R-0143) -- $10,000 per infraction, per animal.

I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,

(b) (6), (b) (7)(C), (b) (7)(D)

(b) (6), (b) (7)(C), (b) (7)(D)

USDA
United States Department of Agriculture

Animal and Plant Health Inspection Service

Animal Care

Fort Collins Office
2150 Centre Avenue
Building B, 3W11
Fort Collins, CO 80526
Phone: 970-494-7478

December 23, 2021

(b) (6), (b) (7)(C), (b) (7)(D)

Dear Complainant,

Thank you for your correspondence dated November 30, 2021. We are reviewing your concerns and assigned tracking number AC22-160. Please allow us enough time (30 to 60 days) to thoroughly look into your concerns. You may submit a request to the Animal and Plant Health Inspection Service (APHIS) Freedom of Information Act (FOIA) office to obtain any publicly available information regarding our review.

FOIA Requests can be submitted three ways:

1. Web Request Form: https://efoia-pal.usda.gov/App/Home.aspx
2. Fax: 301-734-5941
3. US Mail:
   USDA- APHIS- FOIA
   4700 River Road, Unit 50
   Riverdale, MD 20737

Should you have any questions regarding the APHIS FOIA process or need assistance using the Web Request Form **please contact the APHIS FOIA office at 301-851-4102**.

Animal Care is a program within the U.S. Department of Agriculture (USDA) that directs activities to ensure compliance with and enforcement of the Animal Welfare Act and the Horse Protection Act. Animal Care establishes standards of humane treatment for regulated animals and monitors and achieves compliance through inspections, enforcement, education, and cooperative efforts under the Acts.

Please be assured that we will look into your concern(s) and take appropriate action(s).

Thank you for your interest into the humane treatment of these animals.

Sincerely,

Elizabeth Goldentyer, D.V.M.
Deputy Administrator
USDA, APHIS, Animal Care