



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

June 8, 2022

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

Dear Complainant,

Thank you for your correspondence dated June 6, 2022. We are reviewing your concerns and assigned tracking number AC22-780. 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

From: [REDACTED]@nci.rr.com
To: Gibbens, Robert - MRP-APHIS; APHIS-AnimalCare
Subject: [External Email]Prosecute ORA, Inc.
Date: Monday, June 6, 2022 2:32:18 PM

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;
Use caution before clicking links or opening attachments.
Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Dr. Robert Gibbens 6/6/22
Director, Animal Welfare Operations, USDA/APHIS/AC
Via email: robert.m.gibbens@aphis.usda.gov ; animalcare@usda.gov

Dr. Gibbens,

I am writing to you today to file an Official Complaint against ORA Inc. (14-R-0217) for clear violations of the Animal Welfare Act.

As you know, Ora Inc. of Andover, MA. was inspected 4/27/22. The cited violations were so severe that the inspector actually issued two separate reports for the inspection. The first report (attached) was for an extremely rare DIRECT violation. The text of this citation states:

“2.31(c)(7) Institutional Animal Care and Use Committee (IACUC).

On April 27th, 2022, a study was initiated under IACUC protocol #2020-06-13 on 12 New Zealand rabbits involving the application of an experimental contact lens device to both eyes. The humane endpoints on the IACUC approved protocol state that if symptoms of ocular pain become so severe that the animal cannot open the eye and is reluctant to manually manipulating the eye to open, the animal will be euthanized. Research records and research staff indicate that 4 rabbits exhibited severe conjunctival swelling and redness. The research staff further report that the animals were so reluctant to open their eyes that general anesthetic was employed to restrain several animals for experimental observations. Per research staff, observations on this study are usually conducted on alert animals with brief manual restraint.

Failure of the research personnel to adhere to the humane endpoints in the IACUC approved protocol resulted in these animals experiencing unrelieved pain and distress and constitutes a significant change that was not reviewed or approved by the committee.”

It is abundantly clear that these animals suffered horribly at the hands of Ora Inc's bungling staff. This kind of suffering should NEVER have been allowed to occur, and this facility deserves to be severely penalized for these abuses.

This report also delineates another incident in which Ora staff failed to follow an approved protocol and performed an unapproved procedure. Procedures are approved to allow proper safeguards to be in place to prevent unnecessary animal abuse. These failures to follow proper procedures clearly indicate that Ora staff ignores federal regulations on a frequent basis, and thus should be severely penalized.

The second inspection report issued of 4/27/22 (attached) discusses a CRITICAL violation of animal handling regulations in which staff negligence killed several rabbits, likely strangling them because a device was not configured properly to allow sufficient space for the animals necks:

“2.38(f)(1) Critical Miscellaneous.

A study procedure on an IACUC approved protocol involves the use of specialized equipment on anesthetized rabbits in a darkroom. To conduct the procedure, an animal is placed on a platform and the device hood (which weighs approximately 5lb) is lowered to cover the animal's head. When the hood is lowered, there is a gap between the device hood and the platform through which the animal's neck and body extends. The specialized equipment, including the hood, is used to conduct studies on both rodents and rabbits. When in the fully closed position, the gap between the platform and the hood

is approximately 1.5-2". The manufacturer of the equipment sells a device that adjusts the resting height of the hood to increase the gap by several inches to accommodate the larger body size of rabbits.

When this procedure was conducted on a cohort of 18 rabbits on July 13th, 2021, the equipment was not configured to accommodate rabbits. 3 rabbits died acutely and in sequence while being handled in the device. After these adverse events, the investigator continued the study on the remainder of the cohort."

The second inspection report issued on 4/27/22 also discusses additional failures relevant protocols, specifically incomplete protocols, as well as a violation for unqualified personnel because staff was unaware of how to report problems with animal care and treatment.

So, at least four rabbits experienced severe pain due to failure to follow an approved protocol, three rabbits were killed (likely suffocated) due to staff incompetence, likely all rabbits were subjected to improper light cycles which *"can have a variety of impacts on animal health and well being."* Staff also reported *"instances of loss of temperature control in the vivarium."*

It is highly likely that all animals in possession of Ora Inc. (36 according to the USDA inspection report) were killed, abused, or suffered significantly due to staff negligence/incompetence. Therefore this facility clearly deserves the USDA's maximum penalty of \$10,000 per infraction/per animal. A penalty of even 1/3 of this rate would result in a federal fine in the six-figure range.

I am hereby filing an Official Complaint against ORA Inc. (14-R-0217) for serious violations of the Animal Welfare Act which killed and/or abused dozens of animals.

I am calling upon your office to open a new enforcement case relevant to these violations. At the conclusion of your investigation, you must prosecute ORA Inc. (14-R-0217) to the fullest extent of the law, assessing a penalty of \$10,000 per infraction/per animal.

I expect that your office will reply to this correspondence within five business days.

Sincerely,

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

Attachments: 2 USDA Inspection reports

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

		
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United States Department of Agriculture

Animal and Plant Health
Inspection Service

Animal Care

Riverdale, MD Office:
4700 River Road
Unit 84
Riverdale, MD 20737
Voice 301.851.3751
Fax 301.734.4978

VIA: UPS Delivery Service

June 9, 2022

Ora, Inc
300 Brickstone Square
Andover, MA 01810

**OFFICIAL WARNING
NOTICE OF ALLEGED VIOLATION**

Re: Reference number MA220013

Dear Sir or Madam:

We believe that you failed to comply with the Animal Welfare Act (7 U.S.C. § 2131 et seq.) (AWA), and its implementing regulations, as described in the attached Official Warning. Our agency, the Animal and Plant Health Inspection Service (APHIS), is responsible for enforcing the AWA, and regulations and other agriculture laws that help prevent the spread of animal and plant pests and diseases and ensure the welfare of animals.

After providing you with an opportunity for a hearing, we may pursue civil penalties of up to \$10,000, subject to adjustments for inflation, or other sanctions, for each alleged violation described in this Official Warning. Although we have authority to pursue penalties for the type of alleged violation(s) described in this Official Warning, we have decided not to pursue penalties in this instance so long as you comply, in the future, with the AWA and regulations.

What happens if I do not comply in the future? If you fail to comply in the future, we may pursue criminal penalties, or we may pursue civil penalties for the alleged violations described in this Official Warning, in addition to any penalties we may pursue for any future violations.

What should I do if I have questions? If you have any questions concerning this Official Warning, contact Lemnique Wafer, Assistant Director of Field Operations, at lemnique.wafer@usda.gov or call our main office at (970) 494-7478, between 9:00 a.m. and 5:00 p.m. Mountain Standard Time.

I am a small business owner and have comments or concerns regarding APHIS's enforcement of animal and plant health laws. Who should I contact? If you have comments about APHIS's enforcement of animal and plant health laws, please contact Michon Oubichon, the APHIS Small Business Ombudsperson, at (301) 851-2248. If you prefer to comment to someone outside APHIS, contact the Small Business Regulatory Enforcement Ombudsman at <http://sba.gov/ombudsman>, email ombudsman@sba.gov, or 1-888-REG-FAIR. The SBA Ombudsman's office receives comments and annually evaluates federal agency enforcement activities for their responsiveness to the special needs of small businesses.

Sincerely,

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



<p>UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE</p> <p>USDA</p> <p>OFFICIAL WARNING</p> <p>NOTICE OF ALLEGED VIOLATION</p>	CASE NUMBER: MA220013
	ALLEGED VIOLATOR: Ora, Inc
	ADDRESS (<i>City, State, ZIP Code</i>): Andover, MA 01810
<p>The U.S. Department of Agriculture has evidence that on or about the date(s) listed below, you or your organization committed the following alleged violation(s) of Federal laws:</p> <p>Date of Alleged Violation: April 27, 2022</p> <p>9 C.F.R. § 2.38(f)(1) Miscellaneous.</p> <p>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.</p> <p>Date of Alleged Violation: April 27, 2022</p> <p>9 C.F.R. § 2.31(c)(7) Institutional Animal Care and Use Committee (IACUC).</p> <p>With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:</p> <p>Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.</p>	

The Animal and Plant Health Inspection Service (APHIS) published federal regulations to ensure the welfare of animals and help prevent the spread of animal and plant pests and diseases. Since violations of the regulations can have serious and costly impacts that are detrimental to the public interest, APHIS is providing you with an Official Warning for the alleged violation(s) described above. This Official Warning is not to be construed as a final agency action, or as an adjudicated finding of a violation. If APHIS obtains evidence of any future violation of these federal regulations, APHIS may pursue civil penalties, criminal prosecution, or other sanctions for this alleged violation(s) and for any future violation(s). If you have any questions concerning this Official Warning or alleged violation(s), please contact the APHIS official listed in this notice.

APHIS OFFICIAL (Name): Dr. Elizabeth Goldentyer, D.V.M.	OFFICE ADDRESS: 4700 River Road, Unit 84 Riverdale, MD 20737	
APHIS OFFICIAL (Title): Deputy Administrator, APHIS, Animal Care	DATE ISSUED: June 9, 2022	TELEPHONE NUMBER: (970) 494-7478

APHIS FORM 7060

Previous editions may be used

Rev. 4-23-21