Inspection Report

Ora, Inc
300 Brickstone Square
Andover, MA 01810

Customer ID: **507471**
Certificate: **14-R-0217**
Site: 001
ORA INC

Type: FOCUSED INSPECTION
Date: 27-APR-2022

2.31(c)(7) Direct

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.

On April 27th during inspector review of an animal room containing rabbits, a research staff member was observed to administer eye drops (buffered salt solution, or BSS) to one rabbit. On discussion with the lab member, the PI had

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Date: 04-MAY-2022

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Received by Title: IACUC Representative
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directed its administration to assess whether the solution was contributing to adverse reactions being observed in experimental animals. The use of BSS is approved on the protocol for lubrication of the eye throughout the contact lens study, but the experimental assessment of topically administered BSS in a naïve rabbit was not reviewed or approved by the IACUC. Changes in experimental design that include the addition of animal procedures and/or increase the number of animals used must undergo IACUC review and approval prior to being implemented.

Any proposed significant changes to ongoing activities must be reviewed by the IACUC and must be approved by the committee before the research activity is conducted.

To be corrected by May 2nd, 2022, or prior to the use of further animals on this protocol.

A focused inspection was conducted starting on April 27, 2022. This inspection report is limited to the Direct non-compliance identified during that inspection. An additional inspection report will be delivered with the other issues identified during this inspection.

This inspection was conducted April 27-28, 2022 and the exit briefing was conducted with the Vivarium Manager and IACUC Chair on April 28, 2022. A second exit briefing with additional facility representatives was conducted on May 2, 2022.

United States Department of Agriculture
Animal and Plant Health Inspection Service

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Inspection Date: 27-Apr-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
507471	14-R-0217	001	ORA INC	27-APR-2022

Count	Scientific Name	Common Name
000012	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000012	**Total**	