

Inspection Report

Covance Laboratories Inc 3301 Kinsman Boulevard

Madison, WI 53704

Customer ID: 640

Certificate: 35-R-0030

Site: 008

COVANCE LABORATORIES INC

Type: ROUTINE INSPECTION

Date: 09-APR-2019

2.31(c)(7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

In a protocol involving pigs that was approved by the IACUC, the Principal Investigator described the treatment of 40 sites with a dermal resurfacing procedure on the dorsal area (back) and included a diagram of these location of these sites. The study was conducted on one pig with a total of 72 sites, split between left and right areas of the back and sides. While the treatment sites were described as smaller than those originally in the protocol, the study was not conducted according to the approved protocol.

By not following the approved protocol, a research animal may experience greater pain or distress than was justified to or approved by the IACUC.

A Principal Investigator must submit all proposed modifications to the protocol and the IACUC must review and approve such modifications prior to their implementation.

Correct by: This date forward.

2.31(d)(1)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

In a holding protocol involving pigs that were approved by the IACUC, the Principal Investigator indicated that there were procedures that were classified as potentially causing pain or distress that was to be relieved. However, these procedures were not fully described in the protocol and the Principal Investigator did not adequately assure that there were no suitable alternatives, as the literature search did not include any of these terms in the search.

Without a full description of the procedures and an adequate consideration of alternatives for these procedures by the Principal Investigator, neither the IACUC nor the Principal Investigator can assure that pain or distress will be minimized.

Prepared By: SCHNELL MICHAEL, D V M

SCHNELL MICHAEL, D V M USDA, APHIS, Animal Care

SUPERVISORY ANIMAL CARE SPECIALIST 6100

Received By:

Title:

Title:

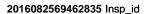
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Page 1 of 2





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The referenced protocol must be revised to include a full description of these procedures and include a relevant consideration of alternatives to procedures that potentially any cause pain or distress. All other protocols that have been approved by the IACUC and any future protocols prior to approval must also contain this information.

Correct by: This date forward for future protocols or prior to use of any previously-approved protocols.

Additional Inspectors

Savage Sara, Veterinary Medical Officer

SCHNELL MICHAEL, D V M Prepared By:

> SCHNELL MICHAEL, D V M USDA, APHIS, Animal Care

SUPERVISORY ANIMAL CARE SPECIALIST 6100 Title:

Received By:

Title:

Date: 10-MAY-2019

Date:

10-MAY-2019



United States Department of Agriculture Animal and Plant Health Inspection Service

Customer: 640 Inspection Date: 09-APR-19

Species Inspected

| Cust No | Cert No | Site | Site Name | Inspection |
|---------|-----------|------|--------------------------|------------|
| 640 | 35-R-0030 | 800 | COVANCE LABORATORIES INC | 09-APR-19 |

| Count | Scientific Name | Common Name |
|--------|------------------------|---|
| 000014 | Canis lupus familiaris | DOG ADULT |
| 000012 | Oryctolagus cuniculus | DOMESTIC RABBIT / EUROPEAN RABBIT |
| 000021 | Ovis aries aries | SHEEP INCLUDING ALL DOMESTIC BREEDS |
| 000034 | Sus scrofa domestica | DOMESTIC PIG / POTBELLY PIG / MICRO PIG |
| 000081 | Total | |