United States Department of Agriculture Animal and Plant Health Inspection Service

2016082569462835 Insp id

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.

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

Prepared By: SCHNELL MICHAEL, D V M USDA, APHIS, Animal Care Date: 10-MAY-2019

Title: VETERINARY MEDICAL OFFICER 6100

Received by Title: SENT VIA EMAIL Date: 10-MAY-2019



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been	approved by	the IACUC	and any futur	e protocols	prior to approva	l 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

Prepared By: SCHNELL MICHAEL, D V M USDA, APHIS, Animal Care Date: 10-MAY-2019

Title: VETERINARY MEDICAL OFFICER 6100

Received by Title: SENT VIA EMAIL Date:

10-MAY-2019



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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	