



Inspection Report

T. B. Holdings L L C
1031 Bing Street
San Carlos, CA 94070

Customer ID: **36525**
Certificate: **93-R-0506**
Site: 003
T. B. HOLDINGS, L.L.C.

Type: ROUTINE INSPECTION
Date: 16-MAR-2016

2.31(e)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

One IACUC approved protocol cited on the August 27, 2015 inspection report was not corrected to provide an adequate rationale for the number of animals to be used.

Protocol 2030 states the number of animals to be used but does not provide a rationale to explain the need for those numbers.

The IACUC is responsible for ensuring that appropriate numbers of animals are used in each approved activity. In order to perform this function the IACUC must know both how many animals are needed for an activity and why that number of animals is needed. It is the responsibility of the IACUC to ensure that each activity involving animals contains and adequate rationale for the number of animals being used.

Previous correction date: Correct by November 17, 2015 for the above protocols and new protocols from this time forward. Other current protocols with inadequate rationales for numbers should be corrected by November 17, 2016.

2.31(e)(3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Protocol 1857 was approved on January 23, 2016 with an inadequate description of animal activities. According to the protocol, pigs in this study are to undergo survival enteroscopic procedures creating areas of radiofrequency ablation to the small bowel. The protocol allows repeated procedures using the same animals and allows the animals to be assigned to a different protocol after the completion of this study. The protocol provides no description regarding the amount of energy being used to create the lesions or the size of the lesions being created. The protocol also states that the animals may undergo multiple ablations by multiple physicians (three to five physicians

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expected) during one session but provides no limits to the number of ablations per procedure or amount of time under anesthesia. While the protocol states that ablation lesions generally heal within three to four weeks, the protocol does not provide a minimum recovery time before either repeating the procedure or moving the animal to another protocol.

It is the responsibility of the IACUC to ensure that animal activities are in compliance with the Animal Welfare Act. In order to perform this function, a complete description of activities using animals must be included in protocols prior to IACUC approval. The facility should ensure that all protocols contain complete descriptions of animal use.

Previous correction date: Correct by November 17, 2015 for the above protocols and new protocols from this time forward. Other current protocols with inadequate rationales for numbers should be corrected by November 17, 2016.

Exit interview conducted with facility representative.

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
36525	93-R-0506	003	T. B. HOLDINGS, L.L.C.	16-MAR-16

Count	Scientific Name	Common Name
000031	<i>Canis lupus familiaris</i>	DOG ADULT
000003	<i>Oryctolagus cuniculus</i>	EUROPEAN RABBIT
000012	<i>Ovis aries aries</i>	SHEEP INCLUDING ALL DOMESTIC BREEDS
000005	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000051	Total	