



Inspection Report

Novartis Institutes For Biomedical Research
5300 Chiron Way
Emeryville, CA 94608

Customer ID: **330337**
Certificate: **93-R-0558**
Site: 001

Novartis Institutes for Biomedical Research

Type: ROUTINE INSPECTION
Date: 03-NOV-2016

2.31(d)(1)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC-approved protocol with reference number 100099 refers to SOT (Standard Operating Technique) # 946, to be used as a guide for procedures that the cotton rats may undergo while on study. At the time of inspection it was discovered that the cotton rats on this study are being administered a compound orally, via gavage, while under anesthesia. Nowhere in the protocol is there any mention of doing the oral dosing under anesthesia. SOT # 946, which describes dosing, specifically calls for manually restraining the conscious animal, and the anesthetics table in the protocol does not mention anesthetic use for this procedure. Whereas using anesthesia rather than manual restraint may be advantageous in order to minimize distress during handling, this practice was not described in the approved protocol, and therefore represents a significant change from what was approved by the IACUC.

Making significant changes to animal use protocols without IACUC review and approval could be detrimental to the animals, as the review process allows consideration of the best methods to minimize pain and distress, as well as ensuring that staff is properly trained in techniques.

To be corrected on this protocol by 12/3/16, and on all protocols from this time forward.

2.31(e)(3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC-approved protocol with reference number 100038 says that the routes of administration of a compound in cotton rats will be carried out per SOT (Standard Operating Technique) # 947, but unfortunately this SOT only covers intranasal administration, whereas the protocol states that compounds may be administered "p.o, i.p, i.t, or s.c." There is no description of how these procedures will be carried out.

Prior to approval, the IACUC must ensure that the investigator has provided a clear and complete description of all the procedures and conditions that the animal will undergo while on study. Failure to provide a complete description could be detrimental to the animals, as it does not allow the IACUC members to fulfill their role in examining possible variations that could improve the experience of the animals on study.

Prepared By: PAMELA SMITH, D V M USDA, APHIS, Animal Care

Date:
08-NOV-2016

Title: VETERINARY MEDICAL OFFICER 6036

Received by Title: ANIMAL WELFARE OFFICER

Date:
08-NOV-2016



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To be corrected on this protocol by 12/3/16, and on all protocols from this time forward.

This inspection and exit interview were conducted with facility representatives.

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
330337	93-R-0558	001	Novartis Institutes for Biomedical Research	03-NOV-16

Count	Scientific Name	Common Name
000007	<i>Canis lupus familiaris</i>	DOG ADULT
000007	Total	