



Inspection Report

Snbl Usa Ltd
6605 Merrill Creek Parkway
Everett, WA 98203

Customer ID: **11124**
Certificate: **91-R-0053**
Site: 001
SNBL USA, LTD

Type: ROUTINE INSPECTION
Date: 10-DEC-2015

2.31(e)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Four IACUC protocols to include 301514-06, 99014-113, 96515-01 and 26515-42 did not have adequate rationales for the numbers of animals to be used. Protocol 301514-06 states in the rationale that "the total number of animals is the minimum needed to properly characterize responses related to Test Article administration and, thus, to meet experimental objectives". The number of animals for dosing is 37 males and 37 females. There is no explanation in the protocol how these numbers were derived. For protocol 99014-113, the rationale states that "the total number of animals is the minimum needed to properly characterize the effects of a high sugar high fat (HSHF) diet on various aspects of the metabolic syndrome in cynomolgus macaques and thus to meet the experimental objectives". The total number of animals to be used in year one is 60. Again, there is no explanation in the protocol how these numbers were determined.

In protocol 96515-01, the rationale for number of animals states "this is a pilot screening study to evaluate the response at three points on an estimated lethality profile. This study will be used to inform doses for a larger study". The total animals to be used will be 48. For protocol 26515-42, the rationale states that "the total number of animals (3 animals/sex/group at terminal and recovery necropsies) is the minimum needed to properly characterize pharmacokinetics and pharmacodynamics and thus to meet experimental objectives". The total number of animals to be used in year one is 54 males and 54 females. Neither protocol provides an explanation as to how these numbers were derived.

The IACUC must ensure that all proposals to conduct an activity involving animals have an adequate rationale that explains why these numbers are necessary in order to ensure that the minimum number of animals are utilized. IACUC approval of activities where an adequate rationale for numbers has not been provided could result in unnecessary animal use. Correct in these protocols, and all current active protocols at the time of the next review, and from this time forward in all new animal activity proposals.

Prepared By: DIANE FORBES, D V M USDA, APHIS, Animal Care

Date:
17-DEC-2015

Title: VETERINARY MEDICAL OFFICER 5053

Received by Title: IACUC ADMINISTRATOR

Date:
17-DEC-2015



Inspection Report

2.33(b)(1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

A cynomolgus macaque (animal #10 in study 265.42) was found dead while restrained in a procedure cage during an infusion study on 10/2/15. Upon inquiring with staff involved, it was discovered that the team carrying out the procedure that day was short-handed due to a scheduling problem.

The research facility must provide adequate staffing to ensure proper monitoring of animals during use and immediate intervention to prevent a serious animal welfare issue. Failure to provide adequate personnel could negatively impact animal welfare; as evidenced in this case. Correct from this time forward by ensuring that there is adequate staffing so that all animals utilized in study procedures are adequately monitored for pain and distress.

3.75(c)(2)

HOUSING FACILITIES, GENERAL.

The floor in room A121 has peeling paint present. There were similarly affected rooms on this wing. Floors with peeling paint are difficult to adequately clean and disinfect, and may create unsanitary conditions. All surfaces should be maintained in good repair in order to allow proper cleaning and sanitization. To be corrected by: March 31, 2016

A team inspection was conducted on December 8 - 10, 2015.

An exit interview was conducted with facility representatives, Dr. Pamela Smith, VMO and Dr. Diane Forbes, VMO.

Additional Inspectors

Smith Pamela, Veterinary Medical Officer

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
11124	91-R-0053	001	SNBL USA, LTD	10-DEC-15

Count	Scientific Name	Common Name
000019	<i>Canis lupus familiaris</i>	DOG ADULT
001596	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000087	<i>Macaca mulatta</i>	RHESUS MACAQUE *MALE
000012	<i>Oryctolagus cuniculus</i>	EUROPEAN RABBIT
000003	<i>Sus domestica</i>	DOMESTIC PIG
001717	Total	