

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 91-R-0053 CUSTOMER NUMBER: 11124	FORM APPROVED OMB NO. 0579-0036
SNBL USA, LTD 6805 Merrill Creek Parkway Everett, WA 98203 Telephone: (425)-407-0121		

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		14			14
9. Non-human Primates	3040	2661	493		3154
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
 (Chief Executive Officer or Legally Responsible Institutional Official)

NOV 14 2008 ✓

SIG

(b)(6), (b)(7)c

DATE SIGNED

11-12-08

APHIS

(AUG 91)

Exemption 1: Housing

The Animal Welfare Act requires that infants older than six months of age are housed according to the floor area and height requirements for their weight, and if housed with the mother, the combined space for each animal by weight is required.¹ The scientific objective of this study requires the assessment of immunological development and function in the infant *Macaca fascicularis*. Following administration of Keyhole Limpet Hemocyanin (KLH) and Tetanus Toxoid (TTx) as a challenge article at 90 and 180 days after birth, blood samples will be collected weekly for five weeks (following the second administration) to assess the immune response. According to previous research, the immunological function of the *Cynomolgus* infant has been shown to be well developed by six months of age.² For this reason it is necessary to assess this response after the infant has reached this age. Additionally, the stress of weaning or relocation to a new location and larger housing with the mother at this critical point in the research project could have a negative impact on the immunological response which the project proposes to assess (e.g. stress upon the mother if new location faces an incompatible social partner, and potential for subsequent effect on lactation, which would directly impact the infant). Therefore it is necessary to provide a housing exemption on the requirements of the AWA for the six week period between when the infants reach six months of age and the end of the research project, when the infants reach 7 ½ months of age.

This exception was reviewed at the February 21, 2007 meeting of the IACUC. A quorum of the committee was present, and the exception was approved unanimously with the provision that additional information was added addressing the impact of weaning or relocation on the research project. This was done, and the revised version was distributed to the IACUC on 02/23/07. Forty-five maternal *Macaca fascicularis* and their infants were approved for participation in this exception during the course of this specific research project. However, none of the infants born on this study had reached the age of six months by 09/30/07. Therefore, this exception is being reported again in our current annual report, with the exact number of animals affected being 30 dams and 30 infants for a total of 60 animals.

¹ 9 CFR, Chapter 1, Subchapter A – Animal Welfare, Part 3 Standards

² “Reproductive Toxicity Testing and Background Control Data in the *Cynomolgus* Monkey” S. Oneda, N. Makori, W. Congdon, Y. Mori, K. Okasaki, S. Meyer [SNBL USA, Ltd. - JSOT, 2005]

Exemption 2 – Sanitation extension

The IACUC approved exemptions for two separate research projects on 05/14/08 and 06/19/08 to extend the AWA requirements for cage sanitation frequency for Nonhuman primates.

The first exemption requested an extension of up to 28-days to mitigate issues of maternal stress and rejection, to minimize the amount of activity in the room, and to prevent new mothers from having their cages changed until a sufficient amount of time had passed to minimize the possibility of infant rejection or injury. This exemption resulted in one extension of the sanitation schedule from 14 to 16 days, effecting 8 animals housed in the room (4 mother/infant pairs). The last infant was born on this project on 07/18/08, and the exemption has no further applicability to this project.

The second exemption requested an extension of up to 28-days due to the high possibility of maternal stress during peri- and post-delivery phase. This exemption was requested to minimize the amount of activity in the room, and to prevent new mothers from having their cages changed out until a sufficient amount of time had passed to minimize the possibility of infant rejection or injury. This exemption resulted in one extension of the sanitation schedule from 14 to 17 days, effecting 36 animals (18 mother/infant pairs). The last infant was born on this project on 09/18/08, and the exemption has no further applicability to this project.

Cages were visually monitored by Husbandry personnel during standard daily room cleaning and by research staff during study procedures. Staff members were directed to report any “grossly soiled” cages (e.g., excessive amounts of debris which may contain unacceptable concentrations of microorganisms or affect normal behavior). If gross contamination was observed, the necessity of cage change would be determined, taking into consideration each animal’s condition and status (e.g., close to delivery, shortly after delivery, excessively nervous animal, etc.). Because cage change activity can affect all animals in the room, the exemption was applied to all cages in the effected room.

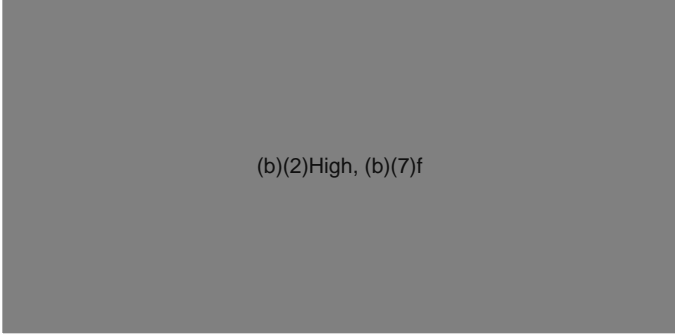
There were no animal health issues reported in relation to these exceptions.

APHIS FORM 7023 (ITEM 3) – Additional Sheet

Customer ID: 11124

Registration Number: 91-R-0053

“List of locations where animals were housed or used in actual research, testing, or experimentation, or held for such purposes”



(b)(2)High, (b)(7)f

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