# Annual Report of Research Facility

**Type or Print:**

**Facility Name:**

**Facility Address:**

**Certificate Number:**

**Customer Number:**

**Telephone:**

### Report of Animals Used for Research, Testing, and Other Experiments

<table>
<thead>
<tr>
<th>Animal Category</th>
<th>Number</th>
<th>Category</th>
<th>Number</th>
<th>Category</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>64</td>
<td>Cat</td>
<td>128</td>
<td>Rabbit</td>
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<tr>
<td>Guinea Pig</td>
<td>99</td>
<td>Horse</td>
<td>6</td>
<td>Non-Human Primates</td>
<td>196</td>
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<tr>
<td>Hamster</td>
<td>25</td>
<td>Sheep</td>
<td>105</td>
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<tr>
<td>Rabbit</td>
<td>24</td>
<td>Other Fish</td>
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<tr>
<td>Other Birds</td>
<td>148</td>
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<tr>
<td>Other Mammals</td>
<td>148</td>
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</tr>
</tbody>
</table>

### Assurance Statements

1. This facility is in compliance with the standards established by the USDA, and it has been certified by the Animal Welfare Program.

2. This facility has been reviewed and approved by the USDA.

3. This facility has been approved by the Institutional Animal Care and Use Committee (IACUC).

4. This facility has been approved by the Institutional Animal Care and Use Committee (IACUC).

**Signature of Institutional Official:**

**Date of Issuance:**

**Form Approved OMB No. 0570-0029**
The 24 dogs assigned to column E of this report were included in toxicology or safety assessment procedures in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 41 CFR 60.01(f)), a limited number of animals must be exposed to test compound dose levels toxic to the animal. Clinical signs produced by some test compounds at toxic dose levels may be distressful or painful to the animal, if only momentarily. To terminate prematurely would invalidate the procedure, requiring its repetition and the consequent use of more animals.
The 60 guinea pigs assigned to column B of this report were included in toxicology or safety assessment procedures in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 4) CFR 60013) positive control animals must be sensitized, then challenged by intradermal injection resulting in a transient inflammatory response, which may or may not be painful to the animals albeit for a strictly limited period. To intercede prematurely would invalidate the procedure, requiring its repetition and the consequent use of more animals.
The 6 rabbits assigned to column E of this report were used for hyperimmunization procedures (polyclonal antibody production) in which adjuvant associated with the antigen of interest produced localized discomfort typical of a subacute inflammatory reaction. The lesions were treated topically to minimize discomfort, and in all cases the minimum quantity of least irritating adjuvant was employed that would not have necessitated the use of additional animals. The protocol permits 10-20 intradermal injection sites which may be pruritic or transiently painful when subjected to normal postural adjustments. The use of systemic analgesics during the several week duration of the process is regarded as inappropriate, since these agents interfere with the antibody production process (e.g., corticosteroids), or have systemic side effects in chronic dosage (appetite suppression, constipation). Although the injection sites are monitored daily for signs of excessive inflammation and treated locally with anesthetics, local anesthetics and antibiotics as indicated, a conservative classification acknowledges the potential for distress associated with what is an idiosyncratic dermatitis.
Primates assigned to column E of this report were used in various toxicology/safety assessment procedures, pharmacologic studies of the inflammatory response or evaluation of the immunomodulatory effects of test compounds.

12 cynomolgus macaques were injected parenterally with compounds intended to produce early physiologic changes associated with systemic shock. Although doses are titrated to produce the minimum physiologic change compatible with the appropriate evaluation of the test anti-inflammatory compound, normal physiologic variation among animals, the side effects of up to four hour injection throughout the test period, and repeated use of the same animals to test a succession of compounds produces transient anorexia and limited signs of depression during the 24-hour post-test period. We feel this could be distressful to the animal and have conservatively assessed the procedure accordingly.

23 squirrel monkeys are used as a model [remains unreadable] in which they are sensitized by antigens in an adjacent vehicle appropriate to the route, dosed with test compound by a variety of routes and then skin tested with the original antigens. Although antigen dose is minimized, systemic reactions include inappetence and depression; local reactions at injection sites are those associated with minimal acute inflammation. Discomfort is attenuated through the use of analgesic drugs but, because an inflammatory condition is induced and clinical signs may appear, it is anticipated that the monkeys may potentially experience the discomfort which human beings feel during the analogous condition.

70 rhesus macaques were included in toxicology or safety assessment procedures in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 43 CFR 600.13) a limited number of animals must be exposed to test compound at dose levels toxic to the animal. Clinical signs produced by some test compounds at toxic levels may be distressful or painful to the animal, if only transiently. To intervene prematurely would invalidate the procedures under the cited regulations, requiring repetition of the study and the consequent use of more animals.