

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

05

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 43-R-0009  
CUSTOMER NO. 1399

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered, include Zip Code)

MIDWEST RESEARCH INST  
425 VOLKER BLVD  
KANSAS CITY, MO 64110  
(816) 753-7600

A by (b)(6), (b)(7)(c)  
02/15/06  
WA

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, 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 animals 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 reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	9				
5. Cats	34	34			34
6. Guinea Pigs	191	396		657	1053
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
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, teaching, 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 approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the 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)  
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

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DATE SIGNED

2/9/06

APHIS FORM 7023  
(AUG 91)

(Replaces VS FORM 18-23 (Oct 88), which is obsolete)

HEADQUARTERS

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Attachment C

Guinea Pigs 01 Oct 2004 - 30 Sep 2005

AUS#		# of GP's	Date received	Pain Level		
				B	C	E
03-13		288	9/23/2004	48	68	172
03-13	b4	90	11/18/2004	0	90	0
03-13		290	12/30/2004	50	74	166
03-13		288	2/3/2005	48	79	161
03-13		288	3/10/2005	45	85	158
<b>Total Counts</b>			<b>1244</b>	<b>191</b>	<b>396</b>	<b>657</b>
			<b># of GP's received</b>	<b>B</b>	<b>C</b>	<b>E</b>
				<b>Pain Level</b>		

2/8/06

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FEB 13 2006





## MIDWEST RESEARCH INSTITUTE

425 Volker Boulevard • Kansas City, Missouri 64110

February 8, 2006

J.E. Slauter, VMO  
Supervisory Animal Care Specialist  
Western Region, Animal Care  
USDA  
2150 Centre Avenue, Building B  
Mail Stop #3W11  
Ft. Collins, CO 80526

*Michael F. Helmstetter, Ph.D.*

Senior Vice President &  
Director of Research Operations

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Customer #: 1399

Registration #: 43-R-0009

Dear Dr. Slauter,

Thank you for your letter of January 23, 2006 requesting clarification of our amended FY2004 annual report (APHIS form 7023). In response to your correspondence, Midwest Research Institute (MRI) reevaluated our original FY2004 and FY2005 submissions and conducted a thorough and in-depth inspection and audit of our laboratory research animal inventory. This exhaustive audit was designed to provide complete clarification and accuracy of our reporting and was based upon documentation from our vendors regarding number of animals shipped, animal receipt records, project specific documentation, and Animal Use Statements (protocols). It is clear that our original reports and amendments did not accurately reflect the quality of our system nor accurate data with respect to animal use at MRI. The attached amendment and data, as well as the information provided below, reflect changes from our original submissions and we would ask that you supersede the previously submitted amendments for FY2004 provided to you by MRI in February 2005 and December 2005 with the attached.

Our review involved balancing Animal Ordering Receipts and an Animal Tracking Records used for per diem counts. This review uncovered a deficiency in our system, which was a lack of readily accessible information for retroactive allocation into different pain categories, leading to the confusion identified in our recent reporting to USDA. Once this deficiency was identified and evaluated, immediate steps were taken to correct the process.

MRI has performed an extensive audit of all procedures to ensure that we are reporting correct numbers. We assigned a Quality Assurance Officer on the MRI staff to review the integrity of the inventory data. The QA Auditor finding is provided in Attachment A.

As a result of this in-depth audit and subsequent internal reporting, we have identified the following:

**FY2004 Annual Report (original submitted November 11, 2004):**

- Confirmation of the number of guinea pigs recorded on our original 2004 USDA report: 2,502 guinea pigs as correct (see Attachment B)
- Confirmation that all guinea pigs are now in the appropriate pain and distress categories per the attached amendment (see Attachment B for details)

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- Confirmation that the 32 dogs listed in our original report should not have been reported
- Rabbit data are accurate as originally reported

Our amended report reflects a Category B increase in guinea pigs (increased by 409) and consequent decreases in Category C (decreased by 309) and Category E (decreased by 100) guinea pigs. These adjustments resulted from 2 findings. First, was the result of an assessment of one of our primary studies and the actual use of several potential test animals. Because the tests mandated specific weight requirements and not all animals met these requirements, 265 guinea pigs outside acceptable weight ranges were never manipulated in the studies. Therefore these animals were reallocated to Category B. Second, an additional 144 guinea pigs were allocated to Category B because they were being held for testing to occur after September 30, 2004.

Lastly, as noted in our December 12, 2005 amendment to our FY2004 report, it was determined that the 32 dogs listed on Column B and Column C were merely housed by MRI for another research facility and were actually included on the other research facility's annual report. As such, MRI performed no research on these dogs and that number has been removed from the attached revised report.

**FY2005 Annual Report (original submitted November 15, 2005):**

The changes in the FY2004 annual report noted above had a direct impact to our FY2005 report submitted on November 15, 2005. Using the same process described above, we have amended the FY2005 report to reflect reallocation of guinea pigs into more appropriate pain categories. The QA audit findings of this allocation and animal use counts can be found in Attachment A. As a result of the guinea pigs identified in Category B in the amended FY2004 report and carried over to FY2005, the number of guinea pigs has increased from 956 in the original annual report to 1,244 in the attached amendment (see Attachment C for details). In addition, there have been changes in the 3 categories, B, C and E which are the direct result of a reassessment of how the animals were used in studies with the same criteria that affected the changes reported for FY2004. Thus, the changes are summarized as follows:

- Amendment of our FY 2005 APHIS form 7023 to increase the number of guinea pigs to 1244 (see Attachment C for details).
- The number of guinea pigs allocated to Category B has been increased from 146 to 191;
- The number of guinea pigs allocated to Category C has been increased from 90 to 396;
- The number of guinea pigs allocated to Category E has been decreased from 720 to 657.

To avoid any reoccurrence of these errors at MRI we have immediately implemented several corrective actions:

- We have involved the IACUC to consult in the development of a system to retroactively confirm and allocate subjects into pain categories.
- We have revised and cross-referenced SOP MRI-1500 "Ordering and Receiving (non-primate) Animals" (Animal Ordering Receipt) with SOP MRI-1502 "Animal Inventory Documentation," as controls to ensure we can balance our animal use accounts appropriately. SOP MRI-1500 captures the number of animals received and that number is verified by two technicians. SOP MRI-1502 cites APHIS form 7023 and contains an animal recording table.
- We have reaffirmed with all Study Directors that they are held responsible for allocating their study animals to the appropriate pain level referencing APHIS form 7023.
- All involved staff is being retrained on the two SOPs, with an emphasis on capturing the correct number of animals in their appropriate categories.
- Hard copies of all inventory information will be forwarded to the Animal Care Supervisor in a timely manner for reporting and retention.
- The Animal Care Supervisor now has an electronic database into which inventory data is continuously fed to produce real-time and on-demand inventory calculations (see example outputs in Attachments B and C).

We regret the confusion that has surrounded our original and subsequent annual report submissions. We fully understand the importance of correct allocations, and we—myself, the technical staff working with our laboratory animals, and the IACUC members—are committed to joint oversight of our inventory processes to ensure the accuracy of our data. We hope the information above and detailed attachments clarify our activities during Fiscal Years 2004 and 2005 and also underscores our commitment to improving processes regarding accountability of our test animals.

Please feel free to contact me

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b6,b7c should you require any additional clarification or information regarding our FY2004 and FY2005 annual reports. We can be reached at (816)-753-7600.

Sincerely,

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**MIDWEST RESEARCH INSTITUTE**  
425 Volker Boulevard • Kansas City, Missouri 64110

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February 8, 2006

The APHIS Form 7023 for fiscal years 2004 and 2005 were audited and found to be correct. Attachments B and C and the supporting spreadsheet data were compared with the shipping/receipt data for fiscal years 2004 and 2005.

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**Attachment A**

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