

Investigative and Enforcement Services

Settlement Agreement

USDA, APHIS, IES
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RESPONDENT:
 Covance Laboratories, Inc.
 Department of Laboratory Animal Medicine
 9200 Leesburg Turnpike
 Vienna, VA 22182-1699

CASE NUMBER VA05018-AC
DUE ON OR BEFORE February 23, 2006
CONTACT Janice Sedgwick
PHONE (301) 734-8759

REVISED

DATE	CITATION	DESCRIPTION
(SEE ATTACHED PAGES)		
PENALTY	58,720	TERMS must be at least 24 inches

Titles 7, 15, 19, and 21 of the United States Code authorize the Secretary of Agriculture to impose civil penalties and other sanctions to resolve violations after providing notice and opportunity for a hearing.

You may waive your right to a hearing and agree to pay the specified civil penalty in settlement of this matter. If you do not agree to the specified penalty, a complaint shall be issued charging you with the violation(s) and seeking higher penalties. You will have the opportunity for a hearing before an Administrative Law Judge to present your case.

I acknowledge that I have been given an opportunity for a hearing and waive such hearing. I neither admit nor deny the violations cited above and agree to pay the civil penalty in full settlement of this matter.

Signature of Respondent: _____ Date: _____

PAYMENT RECORD - FOR IES USE ONLY

Payment Type	Date	Amount	Signature of IES Representative

<u>DATE</u>	<u>CITATION</u> 9 CFR	<u>DESCRIPTION</u>
04 OCT 04	2.38(f)(2) ✓	Miscellaneous. Handling. A primate was handled in a verbally abusive manner.
08 NOV 04	2.38(f)(2) ✓	Miscellaneous. Handling. A primate was handled in a physically abusive manner.
25 NOV 04	2.38(f)(2) ✓	Miscellaneous. Handling. A primate was handled in a physically abusive manner.
14 JUL 05	2.31(d)(1)	Institutional Animal Care and Use Committee (IACUC). Failed to adequately monitor ongoing studies to ensure they were being carried out as proposed. In four studies (D, F, G, H) that were classified as, "No Painful Procedures Anticipated," animals experienced pain and/or distress but received no treatment or relief even though the study protocols indicated veterinary services would be provided.
	2.31(d)(1)(ii)	Protocols for four studies (A, B, C, D) that were known to have potential toxic effects on the animal subjects were approved by the IACUC with the incorrect classification of "No Painful Procedures Anticipated" designated. Also, Study B was amended to reflect a significant change in unexpected mortalities and morbidities, but the protocol classification was not approved and changed.
	2.31(e)(2)	Study I was originally approved by the IACUC for the use of Rhesus monkeys, but when later amended to use a different species, no explanation or justification for the appropriateness of this change was submitted or approved.
	2.31(e)(3)	The protocol animal and care use forms for two studies, G and D, should have contained a more complete description of the effects of the study compound.
	2.33(a)(2)	There were instances where the attending veterinarian's lack of authority was a cause for withholding a recommended treatment, or delaying treatment or euthanasia.
	2.33(b)(3)	Attending veterinarian and adequate veterinary care. Pain and distress were observed in several rabbits due to untreated mild erythema and irritation from ear tag punctures.
	2.36(b)(1)	Annual Report. The animals under Study B were incorrectly reported under the Pain and Distress Category C for the 2004 reporting year.
	3.6(c)(1)(i)	Primary Enclosures, Space. Two dogs were housed in enclosures which did not meet minimum size requirements.

- 3.8 **Exercise for dogs.**
Dogs under Study T were not exercised, and the Protocol for this study did not provide an exemption for exercise for the dogs involved.
- 3.75(a) **Housing facilities, general.**
Areas in Bldg 16 were not kept in good repair and posed a threat to the health and welfare of the animals within. Cracked primate restraint tubes posed injury threat to primates.
- 3.81(a) **Environmental enhancement to promote psychological well-being. Social Grouping.** Failed to commingle one room of non-human primates in accordance with departmental operating procedure for a 10-day period.
- 3.81(c) **Environmental enhancement to promote psychological well-being. Special Considerations.** The plan for environmental enhancement of non-human primates contained no provisions for primates requiring special attention. There did not appear to be an effective mechanism for identifying, documenting and addressing animals displaying signs of psychological distress.
- 3.81(e) **Environmental enhancement to promote psychological well-being. Exemptions.** The IACUC failed to ensure exemptions from participation from environmental enrichment have scientific basis and are addressed in research protocol.