



All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

Animal and
Plant Health
Inspection
Service

Investigative and Enforcement Services
Eastern Regional Office
920 Main Campus Drive, Suite 200
Raleigh, NC 27606

Memorandum

TO: Dr. Allison Khroustalev, Assist. Dir., IES Enforcement

FROM: [REDACTED] Senior Investigator, WV/MD/DE/DC

cc:

DATE: January 5, 2006

SUBJECT: Supplemental Document for IES Investigation VA05018-AC;
Covance Laboratories Inc

Enclosed you will find a document received recently from the legal counsel of a witness named in the investigation involving Covance Laboratories Inc., in Vienna, VA. It appears to be supplemental to Exhibit 8, the affidavit of [REDACTED]. As far as I can tell the new information consists of changes to [REDACTED] testimony, and her concerns were addressed during the course of the investigation.

I believe this investigation is still open pending payment of a stipulation by Covance. The new document should be included with the original case file.

[REDACTED]

JAN 10 2006

V105010AL

SUROVELL MARKLE ISAACS & LEVY PLC

4010 UNIVERSITY DRIVE, SUITE 200
FAIRFAX, VA 22030

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DAVID J. FUDALA*

* ALSO ADMITTED IN D.C.
† ALSO ADMITTED IN MD

December 29, 2005

by first class mail

USDA, APHIS, IES
307 N. Georgia Avenue
Martinsburg, WV 25401

Dear [REDACTED]

re: [REDACTED]

After my client reviewed the affidavit she provided you she noted a couple of matters that needed to be corrected. First, [REDACTED] not in March 2004.

Second, on page 5 of the affidavit, it was written that:

As far as I could tell the study directors appeared to have more control over the welfare of the animals on study than the veterinarians. The only exception was with the stock monkeys where the veterinarians seemed to be able to treat or euthanize animals whenever they felt it was appropriate.

There were several of stock monkeys who needed euthanasia, like #Z90 which had a head tilt, but despite [REDACTED] wishes, [REDACTED] refused to allow them to be euthanized. [REDACTED] believes that there may have been one or two others that required euthanasia but were not given it.

Third, on page 6 of the affidavit, it was written that:

I never had an instance where a veterinary request was not responded to, however some were not responded to immediately.

There is a place on one of the tapes where [REDACTED] refused to receive veterinary requests [REDACTED] had filled out regarding Daiichi monkeys with liquid feces and blood in their stools.

SUROVELL MARKLE ISAACS & LEVY PLC

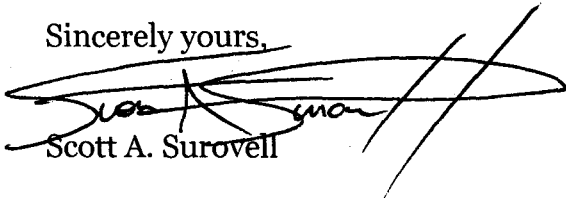
(b)(6)

December 29, 2005

Page 2

Please let me know if you have any questions.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Scott A. Surovell", is written over a horizontal line. The signature is stylized and includes a large, sweeping flourish that extends to the right.

Scott A. Surovell

cc:

(b)(6)

All redactions on this page are pursuant to (b)(6).

[REDACTED] MD/APHIS/USDA

12/19/2005 12:30 PM

To Betty J Goldentyer/NC/APHIS/USDA [REDACTED]

[REDACTED] NC/APHIS/USDA,

cc

bcc

Subject VA05018-AC Covance Laboratories

The subject revised stip has been sent for \$8,720. Attached is a copy of the Revised Settlement Agreement and Cover Letter. If you have any questions please contact [REDACTED]. Thank you.



va05018revised.doc VA05018-AC Ltr REVISED.doc

[REDACTED]
Case Examiner
Investigative and Enforcement Services
Riverdale, MD

[REDACTED]@aphis.usda.gov



DEC 16 2005

United States
Department of
Agriculture

Covance Laboratories, Inc.
Department of Laboratory Animal Medicine
9200 Leesburg Turnpike
Vienna, VA 22182-1699

Animal and
Plant Health
Inspection
Service

REVISED

Dear Sir(s):

Marketing &
Regulatory
Programs Business
Services

Animal and Plant Health Inspection Service (APHIS) enforces regulations to protect the health and care of animals, plants, and agricultural industry. Violations of these regulations jeopardize the animal and plant health systems that are vital to protect American agriculture.

4700 River Road
Riverdale, MD
20737

Our investigation shows that you have violated the United States Code of Federal Regulations as described on the enclosed Stipulation. APHIS laws and regulations provide for administrative and criminal penalties to enforce these regulatory requirements.

The Secretary of Agriculture may, after providing notice and opportunity for a hearing, impose civil penalties or other sanctions. You may, however, waive your right to a hearing and settle this matter by paying \$8,720 by January 16, 2006 and signing the enclosed Stipulation.

Please pay the \$8,720 penalty by certified check or money order made payable to the Treasurer of the United States. Write the Case Number (VA05018-AC) on your check or money order and mail it with the signed Stipulation to:

USDA, APHIS, (General) (VA05018-AC)
P. O. Box 979043
St. Louis, MO 63197-9000

If we do not receive your signed stipulation agreement and payment or notice that you wish to exercise your right to a hearing by January 16, 2006, this matter will be forwarded to the Department's Office of the General Counsel for litigation. The penalty offered in this Stipulation is not relevant to the sanctions APHIS may seek, or that will be assessed after issuance of a formal complaint. You may contact our office at telephone number (301) 734-8684 if you have any questions.

Sincerely,

151
Allison Khroustalev
Assistant Director, Enforcement
Investigative and Enforcement Services

Enclosure

cc: [redacted] IES, ER Dr. B. Goldentyer, AC, ER
[redacted] AC, ER [redacted] IES, WV
APHIS:IES [redacted] 12/15/05 VA05018-AC REVISED



Safeguarding American Agriculture
APHIS is an agency of USDA's Marketing and Regulatory Program

An Equal Opportunity Provider and Employer

12/19 [redacted]



(b)(5)



(b)(5)



(b)(5)





(b)(5)



(b)(5)



(b)(5)



(b)(5)



(b)(5)



(b)(5)



(b)(5)



(b)(5)



(b)(5)



(b)(5)



(b)(5)





OCT 27 2005

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Marketing &
Regulatory
Programs Business
Services

4700 River Road
Riverdale, MD
20737

Convance Laboratories, Inc.
Department of Laboratory Animal Medicine
9200 Leesburg Turnpike
Vienna, VA 22182-1699

Dear Sir(s):

The Animal and Plant Health Inspection Service (APHIS) enforces regulations in order to protect the health and care of animals, plants, and agricultural industry. Violations of these regulations jeopardize the animal and plant health systems that are vital to protect American agriculture.

Our investigation shows that you have violated Federal Regulations as described on the enclosed Civil Penalty Stipulation Agreement form. APHIS laws and regulations provide for administrative and criminal penalties to enforce these regulatory requirements. The amount of the monetary penalty, or possible criminal charges, depends on the number and severity of the violations.

The Secretary of Agriculture may assess a civil penalty for such violations after notice and an opportunity for a hearing. However, you may waive your right to a hearing and settle this matter by paying (b)(5) and signing the **agreement form**. You may voluntarily accept this reduced agreement to avoid further action.

Please pay the civil penalty by certified check or money order made payable to the Treasurer of the United States. Write the Case Number (VA05018-AC) on your check or money order and mail it with the signed agreement form to:

USDA, APHIS, (General) (VA05018-AC)
P. O. Box 979043
St. Louis, MO 63197-9000

If we do not receive your signed stipulation agreement and payment within 30 days, we will seek higher civil or criminal penalties for each violation. You may contact our office at telephone number (301) 734-8684 if you have any questions.

Sincerely,

Allison Khroustalev
Assistant Director, Enforcement
Investigative and Enforcement Services

Enclosure

cc: (b)(6) IES, ER (b)(6) AC, ER
Dr. B. Goldentyer, AC, ER (b)(6) IES, WV

APHIS:IES (b)(6) 10/27/05:VA05018-AC Convance Lab



Safeguarding American Agriculture
APHIS is an agency of USDA's Marketing and Regulatory Program
An Equal Opportunity Provider and Employer

(b)(5)



(b)(5)



(b)(5)



(b)(5)



UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
INVESTIGATIVE AND ENFORCEMENT SERVICES
EASTERN REGION
RALEIGH, NC

REPORT OF INVESTIGATION

Violator(s): **COVANCE LABORATORIES INC.**
9200 Leesburg Turnpike
Department of Laboratory Animal Medicine
Vienna, VA 22182-1699
USDA Registration No. 52-R-0006
(703) 245-2200

Case Number: **VA05018-AC**

Violation(s): 9 CFR Parts 2 and 3

Investigator: (b)(6), (b)(7)(c)
USDA, APHIS, IES
920 Main Campus Dr., Suite 200
Raleigh, NC 27606

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

Date of Report: October 12, 2005

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This document and its contents are not to be distributed
outside your agency, nor duplicated, without prior consent
from USDA, APHIS, Investigative and Enforcement Services.

SYNOPSIS

Violator(s)

Information: Covance Laboratories Inc. is a drug development services company with annual revenues of more than one billion dollars. Covance has global operations in 17 countries and it employs approximately 6700 persons. They are headquartered at 210 Carnegie Center, Princeton, NJ 08540. They offer contract laboratory services such as clinical trials and testing for clients in the biopharmaceutical, environmental and nutritional industries. One such contract laboratory facility is located in Vienna, Virginia. Covance in Vienna, VA is registered as a Research Facility with USDA, APHIS under No. 52-R-0006.

Previous

History: There is no history of violations by Covance Laboratories Inc. on record in the IES Tracking System.

Violation

Events: USDA, APHIS, Investigative & Enforcement Services initiated an investigation in response to a 273 page, formal complaint against Covance Laboratories Inc. for alleged violations of the Animal Welfare Act, which was submitted by the People for the Ethical Treatment of Animal (PETA) to the Secretary of Agriculture on May 16, 2005. The complaint detailed observations recorded by a PETA Investigator who was employed as a lab technician at Covance's Vienna, VA, research facility from March 26, 2004 until March 11, 2005. In addition to written recordings, the PETA Investigator also made digital video and audio recordings of activities witnessed during work hours. The written observations and the video/audio recordings were utilized by PETA as the basis for their allegations.

As a part of our investigation IES requested Animal Care to perform an inspection of the Covance Laboratories Inc. facility. Animal Care conducted a focused inspection concentrating on studies and animals that were either named or indicated in the PETA complaint.

The results of the IES investigation will show where:

- the IACUC failed to adequately monitor ongoing studies to ensure they were being carried out as proposed
- the IACUC approved activities in instances where the literature searches used to determine that alternatives to procedures causing more than momentary or slight pain or distress were not available were determined to be inadequate.
- the IACUC failed to require written justification from the Study Director prior to their withholding of medical treatment from animals experiencing pain and distress.

- the IACUC approved an amendment to a proposed activity without requiring justification for change in species of animal;
- the IACUC approved certain protocols that were classified as “No Painful Procedures Anticipated”, yet the test compounds were known in advance to have potent for toxic effects. The appropriate classification would have required literature search, and that alternatives to procedures causing pain and distress be considered. Protocol Care and Use Forms lacked a description of the compound effects, doses at which they may occur, how they relate to the endpoint and action plan if observed;
- the IACUC approved an amendment to protocol involving change of species but did not require an explanation of justification concerning the appropriateness for this new species;
- the attending veterinarian does not always have appropriate authority to ensure the provision of adequate veterinary care;
- in some instances with rabbits the staff failed to adequately assess the health and well being of animals through daily observations;
- in some instances animals were reported either inappropriately and/or inadequately under the “pain and distress” categories in the Annual Report;
- primary enclosures for two dogs did not meet the minimum space requirements;
- in one study the canine exercise plan was not followed;
- several structural deficiencies existed in the nonhuman primate housing facilities, and primate restraint tubes had large cracks and/or pieces missing from them;
- on one occasion Stock monkeys were not commingled in accordance with primates in accordance with departmental operating procedure for socialization and commingling;
- the plan for environmental enhancement of nonhuman primates contains no special provisions for addressing those showing signs of psychological distress. There does not appear to be an effective mechanism for identifying, documenting and addressing animals displaying stereotypical behavior.
- video segments show two instances where primates were physically abused during handling by lab technicians.

EXPLANATION OF THE EVIDENCE

October 3, 2004

9 CFR

2.38(f)(2)

Miscellaneous. Handling.

Physical abuse was used while handling animals, as evidence by;

Exhibit 4 – CD File document entitled, “Covance Laboratories, Inc. Alleged Violations of the Federal Animal Welfare Act with Video and/or Audio Documentation May 17, 2005” accompanying complaint from PETA as a reference to all video and audio recordings furnished by PETA indicates mishandling by [REDACTED] on 10/3/04 (pp 27)

Exhibit 7 – External computer hard drive furnished by PETA contains video segments taken by [REDACTED] that show the following: (*Refer to a Quicktime Player index number reference point*)

USDA1.mov 01:33:20 – 1:34:30 Rough handling and screaming at primate by [REDACTED] next to him.

Exhibit 8 – Interview Log with [REDACTED] indicates she did take video segments and that segments in the PETA provided hard drive do appear to be the recordings made by her.

Exhibit 9 – Affidavit of [REDACTED] indicates he does appear in this video segment shown to him from video file 1, and that [REDACTED] is also present.

Exhibit 10 – Affidavit of [REDACTED] indicates he does appear in this segment with [REDACTED] shown to him from video file 1.

November 8, 2004

9 CFR

2.38(f)(2)

Miscellaneous. Handling.

Physical abuse was used while handling animals, as evidence by;

Exhibit 4 – File document entitled, “Covance Laboratories, Inc. Alleged Violations of the Federal Animal Welfare Act with Video and/or Audio Documentation May 17, 2005” accompanying complaint from PETA as a reference to all video and audio recordings furnished by PETA indicates mishandling by [REDACTED] on 11/8/04 (pp 52, 53)

Exhibit 7 – External computer hard drive furnished by PETA contains video segments taken by [REDACTED] that show the following: (*Refer to a Quicktime Player index number reference point*)

USDA1.mov 2:57:52 – 2:58:15 Rough handling by [REDACTED] He throws the monkey into the cage with force, then says “Like that?”

Exhibit 8 – Affidavit of [REDACTED] indicates she did take video segments and that segments in the PETA provided hard drive do appear to be the recordings made by her.

Exhibit 10 – Affidavit of (b)(6), (b)(7)(c) indicates he does appear in this segment shown to him from video file 1.

November 25, 2004

9 CFR

2.38(f)(2)

Miscellaneous. Handling.

Physical abuse was used while handling animals, as evidence by:

Exhibit 4 – File document entitled, “Covance Laboratories, Inc. Alleged Violations of the Federal Animal Welfare Act with Video and/or Audio Documentation May 17, 2005” accompanying complaint from PETA as a reference to all video and audio recordings furnished by PETA indicates mishandling by (b)(6), (b)(7)(c) on 11/25/04 (pp 66)

Exhibit 7 – External computer hard drive furnished by PETA contains video segments taken by (b)(6), (b)(7)(c) which show the following: (*Refer to a Quicktime Player index number reference point*)

USDA1.mov 3:34:28 – 3:34:34 (b)(6), (b)(7)(c) hits monkey on head with open hand.

Exhibit 8 – Interview Log with (b)(6), (b)(7)(c) indicates she did take video segments and that segments in the PETA provided hard drive do appear to be the recordings made by her.

Exhibit 9 – Affidavit of (b)(6), (b)(7)(c) indicates he does appear in this video segment shown to him from video file 1, and that it is (b)(6), (b)(7) hand that comes in contact with monkey’s head.

Exhibit 10 – Affidavit of (b)(6), (b)(7)(c) indicates he does appear in this segment shown to him from video file 1.

July 14, 2005

9 CFR

2.31(d)(1)

Institutional Animal Care and Use Committee (IACUC).

IACUC failed to adequately monitor ongoing studies to ensure they were being carried out as proposed. Veterinary care was not provided in certain studies where the protocol indicated it would be, as evidence by:

Exhibit 11 – Animal Care Inspection Report documents where 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.

Exhibit 12 – Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 13 – Covance ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”, and that appropriate veterinary services would be provided if pain was observed.

Exhibit 15 – Covance Request for Veterinary Services shows where animal I57131 on study (b)(4) was showing effects related to test compound but no vet treatment administered.

Exhibit 16 – Request for Veterinary Services shows where animal I57131 on study (b)(4) again showing severe effects related to test compound and that no medical treatment is to be given. Prognosis of animal declines and euthanasia is eventually recommended.

Exhibit 17 - Request for Veterinary Services shows where animal I57114 on study (b)(4) exhibits severe effects related to test compound. Initially, animal was offered treatment for liquid feces but then treatment discontinued at instructions of Client.

Exhibit 18 – Veterinary Directive/Lab Treatment Log for animal I57114 shows where all Pepto-Bismol treatment will be discontinued on the study as per e-note 42052.

Exhibit 19 – Covance ENotes No. 42052 indicates the study clients request to discontinue use of Pepto-Bismol as a treatment to the severe signs of toxicity in animals on study (b)(4)

Exhibit 20 – Series of emails between Covance Study Director (b)(6), (b)(7)(c) and Covance Client regarding the use of Pepto-Bismol as a treatment for animals on study (b)(4) with effects from study compound.

Exhibit 21 – ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”, and that appropriate veterinary services would be provided if pain was observed.

Exhibit 23 – Request for Veterinary Services shows where animal I57523 on study (b)(4) was showing effects related to test compound but no vet treatment administered.

Exhibit 24 – Request for Veterinary Services shows where animal I57527 on study (b)(4) was showing effects related to test compound but no vet treatment administered.

Exhibit 25 – Request for Veterinary Services shows where animal I57528 on study (b)(4) was showing effects related to test compound but no vet treatment administered.

Exhibit 26 – Covance Individual Clinical Observations document for study (b)(4) shows where observations of effects from compounds are documented for animals nos. I57523, I57527, and I57528.

Exhibit 27 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”, and that appropriate veterinary services would be provided if pain was observed.

Exhibit 30 – Request for Veterinary Services shows where animal I57739 on study (b)(4) suffered a complete displaced femur fracture yet received no treatment or pain relief due to study considerations.

Exhibit 31 – Two emails and attached photocopy of radiograph shows where Covance veterinarians were aware of animal I57739 condition on 4/15/05, but did not intend to sacrifice it until 4/18/05.

Exhibit 32 – Individual Clinical Observation record indicates animal no. I57739 was observed with a problematic right leg on days 86, 87 and 90 of the study.

Exhibit 33 – Covance Source Animal Data printout for Study (b)(4) shows where data was continually collected for animal no. I57739 on days 86, 87, 88, 89 and 90 of the study.

Exhibit 34 – Covance Individual Animal Fate Data printout shows where animal number I57739 was sacrificed on 4/18/05.

Exhibit 35 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “Surgical Procedures Have Potential To Elicit Pain”, and that “veterinary assistance will be obtained to provide supportive care or euthanasia, as appropriate to the condition of the animal, or dosing will be stopped, as indicated by responses”.

Exhibit 36 – Individual Clinical Observations printout for Study (b)(4) shows where animal number I57654 exhibited vocalization and teeth grinding during dosing. There were no records available that indicate this animal was provided with any treatment for pain.

2.31(d)(1)(ii)

Institutional Animal Care and Use Committee (IACUC).

IACUC approved certain protocols that were classified as “No Painful Procedures Anticipated”, yet the test compounds were known in advance to have potent for toxic effects. The appropriate classification would have required literature search, and that alternatives to procedures causing pain and distress be considered, as evidence by:

Exhibit 11 – Animal Care Inspection Report documents 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, another study (b)(4) was amended to reflect a significant change in unexpected mortalities and morbidities, but the protocol classification was not approved and changed.

Exhibit 12 – Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 38 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”, yet the Study Director indicates that he is aware of possible inflammation at the dosing site.

Exhibit 40 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”, yet the Study Director indicates that she is aware of compound related effects from a previous study.

Exhibit 42 – Observation records for Animal I56401, shows where suspected compound side affects did occur.

Exhibit 43 – Observation records for Animal I56404, shows where suspected compound side effects did occur.

Exhibit 44 – Observation records for Animals I56417, I56418 and I56419 shows where suspected compound side effects did occur.

Exhibit 45 – Series of Veterinary Treatment Logs and Veterinary Requests show where animal on Study (b)(4) exhibited symptoms of sickness and poor condition, requiring veterinary care to relieve discomfort.

Exhibit 47 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”.

Exhibit 49 – Protocol for Study (b)(4) shows where anaphylactic responses can be anticipated.

Exhibit 50 – Protocol amendment #4 for Study (b)(4) shows where oral lesions were anticipated.

Exhibit 51 – Pre Initiation Meeting Minutes (date unknown) for study (b)(4) (b)(4) indicate known effects from test compound under the paragraph called “Compound Background”, that the test animals should be monitored for any “problems with eating”.

Exhibit 13 – ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”, and that the Study Director (b)(6), (b)(7) is not aware of any toxic/pharmacologic affects of the test material.

Exhibit 15 – Request for Veterinary Services indicates animal I57131 on study (b)(4) was showing effects related to test compound.

Exhibit 16 – Request for Veterinary Services indicates animal I57131 on study (b)(4) again showing severe effects related to test compound.

Exhibit 17 - Request for Veterinary Services shows where animal I57114 on study (b)(4) exhibits severe effects related to test compound.

Exhibit 20 – In an email from Study Director (b)(6), (b)(7)(c) to Client he indicates compound being used on study (b)(4) is a “PPAR” (Peroxisome Proliferator – Activated Receptor).

Exhibit 52 – Notes from a 12/15/04 Pre-Initiation Meeting for a different study using a PPAR compound indicate Study Director (b)(6), (b)(7)(c) is aware of the potential effects associated with a PPAR drug (i.e. heart failure, peri-orbital swelling, edema)

Exhibit 54 – Document furnished by (b)(6), (b)(7)(c) Covance, is an FDA Pre-Clinical and Clinical Assessment for PPAR drugs indicating the facility did have documentation on hand which showed potential toxic effects of PPAR drugs.

Exhibit 55 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”, and that the Study Director is not aware of any toxic/pharmacologic affects of the test material.

Exhibit 56 – Protocol Status Form and attached Amendment No. 1 for Study (b)(4) indicates that all animals in groups 3 and 4 were to be sacrificed on

day 9 of study due to "mortalities and deteriorating condition". No change indicated in Pain/Distress Classification.

Exhibit 57 – The literature search maintained on file by the IACUC for those studies involving continuous infusions or catheterizations does not sufficiently address procedural alternatives.

Exhibit 58 – A second literature search for studies involving continuous infusions or catheterizations provided to Animal Care on 6/29/05 was also found to be inadequate in procedural alternatives.

Exhibit 59 – Affidavit of IACUC Designated Reviewer, (b)(6), (b)(7)(c) indicates the IACUC never received any amendment to study (b)(4) requesting change to the pain/distress classification.

2.31(e)(2)

Institutional Animal Care and Use Committee (IACUC).

IACUC approved an amendment to protocol involving change of species but did not require an explanation of justification concerning the appropriateness for this new species, as evidence by:

Exhibit 11 – Animal Care Inspection Report documents where 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.

Exhibit 12 – Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 60 - ACUC Protocol Status Form for Study (b)(4) was submitted and approved by the IACUC for the use of Rhesus monkeys on 8/31/04.

Exhibit 61 – Protocol Amendment No. 1 submitted by Study Director (b)(6), (b)(7)(c) indicates Client changed species of monkey to be used to cynomolgus. No reason is given. Attached approval from IACUC dated 10/5/04.

Exhibit 63 – Affidavit of Study Director (b)(6), (b)(7)(c) indicates she did not feel it was necessary to justify in a protocol amendment the change in the two species of primates.

Exhibit 59 – Affidavit from IACUC Designated Reviewer (b)(6), (b)(7)(c) indicates she did not receive written justification for change in protocol from study director for study (b)(4) prior to sending it out for approval.

2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).

IACUC approved certain protocols that were classified as "No Painful Procedures Anticipated", yet the test compounds were known in advance to have potential for toxic effects. Consequently, the Protocol Care and Use Forms lacked a description of the compound effects, doses at which they may occur, how they relate to the endpoint and action plan if observed, as evidence by:

Exhibit 11 – Animal Care Inspection Report documents 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.

Exhibit 12 – Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 13 – ACUC Protocol Status Form for Study (b)(4) indicates study was classified as “No Painful Procedures Anticipated”, and that the Study Director was not aware of the possible compound affects.

Exhibit 15 – Request for Veterinary Services indicates animal I57131 on study (b)(4) was showing effects related to test compound.

Exhibit 16 – Request for Veterinary Services indicates animal I57131 on study (b)(4) is again showing severe effects related to test compound.

Exhibit 17 - Request for Veterinary Services shows where animal I57114 on study (b)(4) exhibits severe effects related to test compound.

Exhibit 20 – In an email from Study Director (b)(6), (b)(7)(c) to Client he indicates compound being used on study (b)(4) is a “PPAR” (Peroxisome Proliferator – Activated Receptor).

Exhibit 27 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”, and that Study Director was not aware of possible affects of test material.

Exhibit 52 – Notes from a 12/15/04 Pre-Initiation Meeting for study (b)(4) (b)(4) indicate Study Director (b)(6), (b)(7)(c) was aware of the potential effects associated with a PPAR drug (i.e. heart failure, peri-orbital swelling, edema)

Exhibit 53 – Page from Protocol Study No. (b)(4) indicates “high dose should result in toxicity”, indicating Study Director was aware of potential toxic effects from compound.

Exhibit 54 – Document furnished by (b)(6), (b)(7)(c) Covance, is an FDA Pre-Clinical and Clinical Assessment for PPAR drugs indicating the facility did have documentation on hand which showed potential toxic effects of PPAR drugs.

2.33(a)(2)

Attending veterinarian and adequate veterinary care.

Failure to assure that the attending veterinarian has the appropriate authority to ensure provision of adequate veterinary care, as evidence by:

Exhibit 11 – Animal Care Inspection Report documents instances where the attending veterinarian’s lack of authority was a cause for withholding a recommended treatment, or delaying treatment or euthanasia.

Exhibit 12 – Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 65 – Request for Veterinary Services for animal I57607, study (b)(4) (b)(4) shows where the attending veterinarian and Study Director agreed to early euthanasia, but that Study Director needed to contact client to discuss other options. Client, IACUC members, and DLAM Director the attending

veterinarian's decision to provide euthanasia, on 12/30/04, and animal remained on study 5 more days.

Exhibit 66 – Veterinary Directive/Lab Treatment Log shows where animal I57607 remained under treatment on Study (b)(4) until 1/3/05.

Exhibit 27 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as “No Painful Procedures Anticipated”, and that appropriate veterinary services would be provided if pain was observed.

Exhibit 30 – Request for Veterinary Services for animal I57739, study (b)(4) (b)(4) shows where animal remained untreated in cage with broken leg for three days after recommended euthanasia, for study considerations.

Exhibit 31 – Two emails and attached photocopy of radiograph shows where Covance veterinarians were aware of animal I57739 condition on 4/15/05, but did not intend to sacrifice it until 4/18/05.

Exhibit 32 – Individual Clinical Observation record indicates animal no. I57739 was observed with a problematic right leg on days 86, 87 and 90 of the study.

Exhibit 33 – Covance Source Animal Data printout for Study (b)(4) shows where data was continually collected for animal no. I57739 on days 86, 87, 88, 89 and 90 of the study.

Exhibit 34 – Covance Individual Animal Fate Data printout shows where animal number I57739 was sacrificed on 4/18/05.

Exhibit 67 – Affidavit of (b)(6), (b)(7)(c) indicates her reasons for not providing pain relief to animal I57739 during time with broken leg.

Exhibit 69 – Request for Veterinary Services for animal I56620, study (b)(4) (b)(4) shows where the attending veterinarian recommended a 5 day treatment of systemic antibiotic but the treatment for a digit laceration, but it was never administered at the instructions of the Study Director. Topical antibiotic used instead.

Exhibit 70 – Request for Veterinary Services for animal I57452, study (b)(4) (b)(4) shows where attending veterinarian withheld treatment of Pepto Bismol for one day until client approval could be obtained. Prognosis for animal changed from “guarded” to “very guarded”.

Exhibit 71 – Request for Veterinary Services for animal I56999, study (b)(4) (b)(4) shows where attending veterinarian recommended euthanasia on 2/10/05, was delayed until after study parameters could be collected over next four days. Client preferred option of Baytril was given.

Exhibit 72 – Request for Veterinary Services, dated 2/11/05, shows where a second veterinarian, (b)(6), (b)(7)(c) recommends animal I56999 be sacrificed.

Exhibit 73 – Veterinary Directive/Lab Treatment Log for animal I56999 shows where treatment with Baytril continued for five days.

Exhibit 74 – Observation record shows the condition of animal I56999 on day of sacrifice.

Exhibit 75 – Pathology report for animal I56999 shows it was sacrificed on 2/15/05.

Exhibit 76 – Request for Veterinary Services for animal I56997, study (b)(4) (b)(4) shows where attending veterinarian recommended topical and systemic treatment for swollen eyes was delayed unnecessarily by client.
Exhibit 77 – Veterinary Directive/Lab Treatment Log for animal I56997 shows where Client overruled recommended treatment of attending vet.

Covance Laboratory Inc. rebuttal to the issue of attending veterinary authority is addressed in their appeal to the Animal Care Inspection Report shown in Exhibit 115. The appeal includes a response by (b)(6), (b)(7)(c) under a section entitled "Certification of (b)(6), (b)(7)(c) and she specifically addresses her veterinary responses to certain animals in this section. She also addresses her responses in an affidavit (See Exhibit 67) In addition, DLAM Director, (b)(6), (b)(7)(c) addresses some of the same animals in his affidavit. (See Exhibit 68) Finally, the Department Operating Procedure, NA-TOPS.922, Veterinary Examination and Treatment of Animals (Exhibit 118) list the required protocol for veterinary response at Covance.

2.33(b)(3)

Attending veterinarian and adequate veterinary care.

Failure to adequately assess the health and well being of animals through daily observations, as evidence by:

Exhibit 11 – Animal Care Inspection Report documents pain and distress being observed in rabbits due to untreated erythema and irritation from ear tag puncture sites. Staff mentioned signs of discomfort from the ear tagging normally seen for about 2 days post procedure.

Exhibit 12 – Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 78 – Digital photograph of ear for rabbit no. 1277 (study (b)(4) shows edge of ear rolling and erythema resulting from eartag.

Exhibit 79 – Digital photograph of ear for rabbit no. 1256 (study shows where ear tag is causing the edge of ear to roll.

Exhibit 80 – Digital photograph of ear for rabbit no. 1274 (study shows where ear tag is causing the edge of ear to roll.

Exhibit 81 – Digital photograph of ear for rabbit no. 1274 (study shows where ear tag is causing inflammation and the edge of ear to roll.

Exhibit 82 – Individual Clinical Observation records for rabbits on Study (b)(4) make no mention of ear rolling or anything beyond observations at dermal scoring sites.

Covance refutes this citation in their "appeal" document (Exhibit 122); however, their own observation records that are included with this document make no mention of the observation of ear scabs in rabbits until after USDA brought it to their attention on June 10, 2005. Otherwise, no mention of the symptoms appears in their observation records.

2.36(b)(1)

Annual Report.

Annual report failed to assure that professionally acceptable standards governing the appropriate use of anesthetic, analgesic and tranquilizing drugs were followed by the researched facility, as evidenced by;

Exhibit 11 - Animal Care Inspection Report documents that animals under study B were incorrectly reported under the Pain and Distress category C.

Exhibit 12 - Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 40 - ACUC Protocol Status Form shows where Study (b)(4) was classified as "No Painful Procedures Anticipated", yet the study director was aware of possible toxic effects from the compound

Exhibit 83 - Annual Report shows where 1,246 Non-human Primates were reported under pain and distress category C for the year 2004.

Exhibit 42 - Observation records for Animal I56401, Study (b)(4) shows where suspected compound side affects did occur.

Exhibit 43 - Observation records for Animal I56404, Study (b)(4) shows where suspected compound side affects did occur.

Exhibit 44 - Observation records for Animals I56417, I56418 and I56419 Study (b)(4) shows where suspected compound side affects did occur.

Exhibit 45 - Series of Veterinary Treatment Logs and Veterinary Requests show where animal on Study (b)(4) exhibited symptoms of sickness and poor condition, requiring veterinary care to relieve discomfort.

2.36(b)(6)

Annual Report.

Annual Report failed to accurately state the number of animals upon which research was conducted involving accompanying pain and distress to the animals, as evidenced by;

Exhibit 11 - Animal Care Inspection Report documents that animals under study E were reported under the Pain and Distress category C. Protocol was amended to reflect unexpected mortalities and morbidities but Protocol ACUC form was never changed to show there was non-surgical pain or distress.

Exhibit 12 - Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 55 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as "No Painful Procedures Anticipated."

Exhibit 56 - Protocol Status Form and attached Amendment No. 1 for Study (b)(4) indicates that all animals in groups 3 and 4 were to be sacrificed on day 9 of study due to "mortalities and deteriorating condition". No change indicated in Pain/Distress Classification.

Exhibit 59 - Affidavit of IACUC Designated Reviewer, (b)(6), (b)(7)(c) indicates the IACUC never received any amendment to study (b)(4) requesting change to the pain/distress classification.

2.36(b)(7)

Annual Report.

Annual Report failed to accurately state the number of animals upon which research or surgery was conducted involving accompanying pain and distress to the animals, and for which the use of appropriate pain relieving drugs would have adversely affected the procedures, results or interpretations, as evidenced by;

Exhibit 11 - Animal Care Inspection Report documents that animals under studies D, F and H should have all been reported under Category E for Pain and Distress, but were not.

Exhibit 12 - Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 13 - ACUC Protocol Status Form for Study (b)(4) indicates study was classified as "No Painful Procedures Anticipated", and that the Study Director was not aware of the possible compound affects.

Exhibit 15 - Request for Veterinary Services indicates animal I57131 on study (b)(4) was showing effects related to test compound.

Exhibit 16 - Request for Veterinary Services indicates animal I57131 on study (b)(4) is again showing severe effects related to test compound.

Exhibit 17 - Request for Veterinary Services shows where animal I57114 on study (b)(4) exhibits severe effects related to test compound.

Exhibit 18 - In an email from Study Director (b)(6), (b)(7)(c) to Client he indicates compound being used on study (b)(4) is a "PPAR" (Peroxisome Proliferator - Activated Receptor).

Exhibit 54 - Document furnished by (b)(6), (b)(7)(c) Covance, is an FDA Pre-Clinical and Clinical Assessment for PPAR drugs indicating the facility did have documentation on hand which showed potential toxic effects of PPAR drugs.

Exhibit 21 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as "No Painful Procedures Anticipated", and that appropriate veterinary services would be provided if pain was observed..

Exhibit 23 - Request for Veterinary Services shows where animal I57523 on study (b)(4) was showing effects related to test compound but no vet treatment administered.

Exhibit 24 - Request for Veterinary Services shows where animal I57527 on study (b)(4) was showing effects related to test compound but no vet treatment administered.

Exhibit 25 - Request for Veterinary Services shows where animal I57528 on study (b)(4) was showing effects related to test compound but no vet treatment administered.

Exhibit 26 - Covance Individual Clinical Observations document for study (b)(4) shows where observations of effects from compounds are documented for animals nos. I57523, I57527, and I57528.

Exhibit 35 - ACUC Protocol Status Form for Study (b)(4) shows where study was classified as "Surgical Procedures Have Potential To Elicit Pain",

and that "veterinary assistance will be obtained to provide supportive care or euthanasia, as appropriate to the condition of the animal, or dosing will be stopped, as indicated by responses".

Exhibit 36 - Individual Clinical Observations printout for Study (b)(4) shows where animal number I57654 exhibited vocalization and teeth grinding during dosing. There were no records available that indicate this animal was provided with any treatment for pain.

3.6(c)(1)(i)

Primary Enclosures, Space.

Two dogs were housed in enclosures which do not meet minimum size requirements, as evidenced by;

Exhibit 11 - Animal Care Inspection Report documents that two dogs were measured and found to require 8.5 sq. ft. of floor space, yet they enclosures provided only 7.3 sq. ft.

Exhibit 84 - Video Clip MOV00315.MPG shows dog turning within its' enclosure in Bldg. 16, Room 1593 that was measured by Animal Care Inspector, (b)(6), (b)(7)(c)

Exhibit 84 - Video Clip MOV00320.MPG shows dog in it's' enclosure in Bldg. 16, Room 1593, and having to place feet on resting board in order to turn around.

Exhibit 85 - Memo from IES Investigator (b)(6), (b)(7)(c) states that he was the photographer of the video clips mentioned above, and provides an explanation of what they show.

3.8

Exercise for dogs.

Failure to follow plan to provide dogs with the opportunity for exercise, as evidenced by;

Exhibit 11 - Animal Care Inspection Report documents that dogs under study T were not exercised, and that the Protocol for this study did not provide an exemption for exercise for the dogs involved.

Exhibit 12 - Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 88 - Covance Department Operating Procedure NA-TOPS.213, Methods of Canine Exercise, indicates requirements for exercise which include commingling, or alternative methods for exercise when exemptions for commingling exist.

Exhibit 89 - ACUC Protocol Status Form for Study (b)(4) shows where Study Director requested and was granted an exemption to commingling only by the IACUC.

Exhibit 90 - On line room log for study (b)(4) (with attached note from (b)(6), (b)(7)(c) shows where there was no record of the dogs having been provided with exercise as per the department operating procedure.

3.75(a)

Housing facilities, general.

Failure to keep housing facilities for nonhuman primates in good repair so that they protect the animal from injury or disease, as evidenced by;

Exhibit 11 - Animal Care Inspection Report documents areas in Building 16 that are not being kept in good repair, and which pose threat to the health and welfare of the animals within. Also shows where cracked primate restraint tubes pose injury threat to primates.

Exhibit 91(a-c) – Photos show damaged, peeling drain in Room 1450.

Exhibit 92(a-f) – Photos show damaged floor areas with peeling paint and retained water in Room 1130.

Exhibit 93(a-d) – Photos show previously damaged ceiling area in Room 1480 that was incompletely repaired.

Exhibit 94(a-c) – Photos show Plexiglas restraint tubes on hand in Room 1472.

3.81(a)

Environmental enhancement to promote psychological well-being. Social Grouping. Failure to commingle non-human primates in accordance with departmental operating procedure, as evidenced by;

Exhibit 11 - Animal Care Inspection Report documents that between 1/19/05 and 2/17/05 stock animals were not commingled in accordance with the operating procedure.

Exhibit 12 – Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 95 – Covance Department Operating Procedure NA-TOPS.222, Methods of Non-Human Primate Socialization and Commingling, indicates stock primates are to be gradually commingled up to a minimum of 15 hours per day of the week (excluding weekends) following release from quarantine.

Exhibit 96 – Covance Stock Colony Protocol indicates non-human primates will be commingled according to SOP for psychological enrichment.

Exhibit 97 – On line Comments document for Project P (b)(4) show where monkeys were removed from quarantine on 1/19/05 and were not commingled again until 2/17/05.

Exhibit 98 – Affidavit of (b)(6), (b)(7)(c) shows where she was the lead technician in charge of stock monkeys during January and February of 2005, and that the primates indicated on the Comments document were not commingled as a result of personnel error.

3.81(c)

Environmental enhancement to promote psychological well-being. Special Considerations.

Failure to develop a plan for environment enhancement of non-human primates that addresses those requiring special attention such as those showing signs of being in psychological distress through behavior or appearance, as evidenced by;

Exhibit 11 - Animal Care Inspection Report documents the plan for environment enhancement of non-human primates, outlined in NA-TOPS.201, contains no provisions for primates requiring special attention; and that that there does not appear to be an effective mechanism for identifying, documenting and addressing animals displaying stereotypical behavior or other signs of psychological distress.

Exhibit 12 - Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 99 - Department Operating Procedure NA-TOPS.201, General Animal Care and Environmental/Psychological Enrichment-Felines, Canines, Primates, and Swine, contains no provisions for dealing with stereotypical behavior or psychological distress.

Exhibit 100 - Pre-Study Examination shows where Animal Z208 was exhibiting "alopecia from self trauma"

Exhibit 84 - Video Clip MOV00340.MPG shows primate I58344 exhibiting stereotypical "picking" or "grooming" behavior.

Exhibit 84 - Video Clip MOV00342.MPG shows primate I58335 exhibiting stereotypical "cage wiping" behavior.

Exhibit 101(a, b) - Two Requests for Veterinary Services for Animal Nos. Z00666, study no. (b)(4) (stock monkey) and a guinea pig on (b)(4) were the only vet requests Animal Care Inspectors could back to January 2004 that related to stereotypical behavior in animals.

Exhibit 7 in this report consists of an external computer hard drive received from PETA on 7/7/05. Video segments located on files USDA1.mov and USDA2.mov of the hard drive were viewed by Animal Care Veterinarians (b)(6), (b)(7)(c)

(b)(6), (b)(7)(c) The complete circumstances surrounding the filming of the segments could not be established, making it difficult to identify certain animal behavior being exhibited in the segments as "stereotypical". Absolute authenticity of the segments was not possible either. Consequently, these segments indicative of stereotypies were not included as evidence to support the violation of 9 CFR 3.81. However, the segments within these files that reflect possible stereotypical behavior can be located at index tracking points 28:22 - 29:40, 1:09:29, 1:35:09 - 1:36:42, 2:07:35, 2:43:37 - 2:43:43 on USDA1.mov, and at 1:22:53 - 1:25:43 on USDA2.mov.

3.81(e)

Environmental enhancement to promote psychological well-being.

Exemptions.

Failure by the IACUC to recognize that the basis for exempting animals in certain studies from environmental enrichment lacked any documented scientific basis, as evidenced by;

Exhibit 11 - Animal Care Inspection Report documents failure by the IACUC to ensure exemptions from participation from environmental enrichment have scientific basis and are addressed in research protocol.

Exhibit 12 – Study Number Identification List shows Covance Study Numbers and the corresponding Identification Code that was referenced in the Animal Care Inspection Report. (Used for CBI protected material)

Exhibit 21 – ACUC Protocol Status Form for Study (b)(4) shows where study was approved as exempt from commingling due to “possible negative effects”. On the same form the Study Director indicated not being aware of possible toxic/pharmacologic effects of the test material.

Exhibit 102 – ACUC Protocol Status Form for Study (b)(4) shows where study was approved as exempt from commingling due to “possible negative effects”. On the same form the Study Director indicated not being aware of possible toxic/pharmacologic effects of the test material.

Exhibit 103 – ACUC Protocol Status Form for Study (b)(4) shows where study was approved as exempt from commingling due to “possible negative effects”. On the same form the Study Director indicated not being aware of possible toxic/pharmacologic effects of the test material.

OTHER EVIDENCE

Exhibit 1 – Formal complaint letter from PETA addressed to Secretary of Agriculture, Michael Johanns, alleges violations of the federal Animal Welfare Act by Covance Laboratories Inc.

Exhibit 2 – DVD received from USDA, APHIS, Animal Care marked, “Covance - - Vienna, VA. Drug Testing on Primates A PETA Undercover Investigation April 26, 2004 – March 11, 2005 www.covancecruelty.com”. Provided by PETA with complaint as verification of existence of federal violations at Covance Labs.

Exhibit 3 – CD File, CrueltyComplaint_May17.doc, is document entitled, “Covance Laboratories, Inc. Alleged Violations of the Federal Animal Welfare Act May 17, 2005” accompanying complaint from PETA to USDA contains alleged observations and notations by PETA Investigator operating under cover as an employee at Covance Laboratories Inc. in Vienna, VA., between 4/26/04 and 3/9/05.

Exhibit 4 – Also contains the electronic file of the daily journal furnished by (b)(6), (b)(7)(c) indicating her observations during her employment at Covance. It was furnished via email to (b)(6), (b)(7)(c) by (b)(6), (b)(7)(c) attorney, (b)(6), (b)(7)(c) on 10/6/05.

Exhibit 5 – CD File document entitled, “Covance Laboratories, Inc. Alleged Violations of the Federal Animal Welfare Act (Addendum) June 13 2005” provides investigator notes and PETA annotations for additional video/audio footage and “improved footage from original DVD sent with Complaint.

Exhibit 6 – DVD received from Animal Care marked “Peta 6-14-05 Covance, Vienna, VA Addendum Edit” was provided by PETA as a clearer and more discernable copy of video and audio footage of violation activity at Covance.

Exhibit 7a – Letter and business card from Mary Beth Sweetland that accompanied computer hard drive to USDA.

Exhibit 14 – IACUC Minutes for July 12, 2004 shows where Study No. (b)(4) was approved by IACUC designated reviewer and without full committee review.

Exhibit 22 – IACUC Minutes for November 2004 shows where Study Nos. (b)(4) (b)(4) (Amendment 2) and (b)(4) were approved by designated reviewer and without full committee review.

Exhibit 28 - Study No. (b)(4) Protocol, issued by Study Director (b)(6), (b)(7)(c), on 2/14/04, indicates within on page 8, under paragraph titled “Reason for Dosage Design” that toxic effects from compound are to be expected.

Exhibit 29 – IACUC Minutes for December 2004 show where Study Nos. (b)(4) and (b)(4) were approved by designated reviewer and without full committee review.

Exhibit 37 - ACUC Protocol Status Form for Study (b)(4) shows where study was originally classified by Study Director as painful procedure prior to change on 1/4/05.

Exhibit 39 – Study No. (b)(4) Protocol, issued by Study Director (b)(6), (b)(7)(c) on 1/14/04, provides outline of study procedure for that protocol.

Exhibit 41 - IACUC Minutes for June 7, 2004 shows where Study No. (b)(4) was approved by IACUC designated reviewer and without full committee review.

Exhibit 46 – Individual Animal Fate Data record lists all animals assigned to Study (b)(4)

Exhibit 48 – IACUC Minutes for April 6, 2005 shows where Study No. (b)(4) (Amendment 4) was approved by IACUC designated reviewer and without full committee review. (Note that

OTHER EVIDENCE (Con't)

the minutes did not include the usual copy of the attached Protocol ACUC Review Form for Study (b)(4) (Amendment 4).

Exhibit 62 – Email from Study Director (b)(6), (b)(7)(c) indicates removal of rhesus monkeys from study (b)(6), (b)(7)(c)

Exhibit 64 – Portion of the IACUC Minutes from September of 2004 shows where Study Director (b)(6), (b)(7)(c) mentions a side effect from a preliminary study to (b)(4) may not take place in cynomolgus monkeys (as opposed to rhesus).

Exhibit 68 – Affidavit of (b)(6), (b)(7)(c) documents his recollection of veterinary care provided to animal I56999 on and about 2/9/05; and animal I57607 on or about 12/30/04. He also attests to the attending veterinarian's authority at Covance Laboratory Inc., at Vienna, Va. He addresses never having observed burns caused by the ECG machines; he addresses the level of his observation of stereotypical behavior in primates at Covance; he explains what appears to be an error in his work time sheets; and he explains the "on call" veterinarian program.

Exhibit 86 – Photograph of a canine cage in Building 16, Room 1593 at Covance Lab shows where floor space is somewhat restricted by resting board.

Exhibit 87 – Photograph of a canine cage in Building 16, Room 1593 at Covance Lab shows where floor space is somewhat restricted by resting board.

Exhibits 104 – 112 consist of affidavits from a variety of technicians and supervisors who were interviewed due to their mention in the complaint from PETA, and in order to verify activities and ascertain general information on animal care and treatment concerns. These affidavits are in addition to those submitted by Technicians (b)(6), (b)(7)(c) that were shown in Exhibits 9, 10 and 98 (respectively). The testimony provided by the affiants do not further support the violations cited in this report. However, they may be helpful in your assessment of our investigative findings.

Exhibit 113 – Curriculum Vitae for (b)(6), (b)(7)(c) provided by Covance Laboratories Inc. shows her work experience and background in handling laboratory animals.

Exhibit 114 – Procedure certification checklist provided by Covance Laboratories shows (b)(6), (b)(7)(c) (b)(6), (b)(7)(c) training certification and dates of certification.

Exhibit 115 – The Operating Instructions and technical specifications for the Eclipse Plus Electrocardiograph machine were provided by Covance Laboratories and this is the type of ECG machines they use exclusively. Based upon the information when the machine is operating in the ECG mode (as opposed to the defibrillator mode) the potential for causing burns is minimal if not non-existent.

Exhibit 116 – Research regarding the current in Patient –Connected Leads from ECG machines indicates that since the early 1970's the current flow through any such lead was well below that which could be felt, much less burn the patient.

Exhibit 117 – Affidavit from (b)(6), (b)(7)(c) was submitted as testimonial support that she never provided advance notice to anyone at Covance Laboratories Inc. about her intended inspections.

Exhibit 118 – Covance Laboratories Inc. appeal response to USDA, Animal Care Inspection Report of July 14, 2005, refutes many of the citations by Animal Care and provides documentation and testimony to support their position.

OTHER EVIDENCE (Con't)

Exhibit 119 – Covance Laboratories, Department Operating Procedure, NA-TOPS.922, Veterinary Examination and Treatment of Animals shows where the attending veterinarian obtains and documents authorization for treatment from the study director or designee, but if they are not immediately available the veterinarian can make emergency decisions.

Exhibit 120 – IACUC Membership List shows members as of May of 2005.

Exhibit 120 – Animal Welfare Complaint shows where Covance Laboratories was reported for violations of the AWA relating to irradiation surgery in primate, and that Animal Care did respond to the complaint on 11/16/04.

Exhibit 121 – Application for Registration for Covance Laboratories Inc. in Vienna, VA is current.

Exhibit 122 – Covance document entitled, “Re: Covance Laboratories Inc. (ID: 507); Reply to Inspection Report Issued on July 14, 2005 to Covance’s Vienna, VA Facility (Site 001), refutes many of the inspection citations by Animal Care, and includes documentation to support their dispute. **Note that this document also contains further certification from (b)(6), (b)(7)(c) about her decisions and veterinary care response that relate to animal cited in the Inspection Report.**

EXHIBIT LIST

- Exhibit 1** – Complaint letter from PETA to USDA Secretary Michael Johanns, dated 5/16/05. (12 pages)
- Exhibit 2** – DVD received from USDA, APHIS, Animal Care marked, “Covance - - Vienna, VA. Drug Testing on Primates A PETA Undercover Investigation April 26, 2004 – March 11, 2005 www.cocovancecruelty.com”
- Exhibit 3** – CD containing files: “CrueltyComplaint_May17.doc” , is text document entitled, “Covance Laboratories, Inc. Alleged Violations of the Federal Animal Welfare Act May 17, 2005”; flu15500.PDF, is current Covance USDA Registration as a Research Facility, No. 35-R-0030. Received from IES Region with Investigation Request on 6/2/05.
- Exhibit 4** – CD contains 2 files (1) document entitled, “Covance Laboratories, Inc. Alleged Violations of the Federal Animal Welfare Act with Video and/or Audio Documentation May 17, 2005” accompanying complaint from PETA. (2) File named “Gray Log Notes”, authored by (b)(6), (b)(7)(c)
- Exhibit 5** – CD contains file “Alleged Violations of the Federal Animal Welfare Act at Covance ADDENDUM.DOC”, and consists of text document entitled, “Covance Laboratories, Inc. Alleged Violations of the Federal Animal Welfare Act (Addendum) June 13 2005”, provided by PETA and received from Animal Care on 6/16/05.
- Exhibit 6** – DVD received from Animal Care marked “Peta 6-14-05 Covance, Vienna, VA Addendum Edit”. Received from IES Regional Office on 6/20/05.
- Exhibit 7** – External computer hard drive containing files USDA1.mov, USDA2.mov and USDA3.mov. Provided by PETA (Mary Beth Sweetland) to USDA, Animal Care. Received from IES Regional Office via FedEx on 7/7/05
- Exhibit 7a** – Letter and attached business card from Mary Beth Sweetland, PETA, dated 6/10/05.
- Exhibit 8** – Affidavit of (b)(6), (b)(7)(c) dated 10/05.
- Exhibit 9** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 10** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 11** – Animal Care Inspection Report, dated 7/14/05 for Covance Laboratories Inc.
- Exhibit 12** – Study Number Identification List created by Animal Care to show corresponding identification codes used in inspection report.
- Exhibit 13** – Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 14** – Covance IACUC Minutes for July 12, 2004. Includes attached Protocol ACUC Review Form for Study (b)(4)
- Exhibit 15** – Covance Request for Veterinary Services, dated 10/15/04, for Animal No. I57131, Study No. (b)(4)
- Exhibit 16** – Covance Request for Veterinary Services, dated 11/17/04, for Animal No. I57131, Study No. (b)(4)
- Exhibit 17** – Covance Request for Veterinary Services, dated 11/18/04, for Animal No. I57114, Study No. (b)(4)
- Exhibit 18** – Covance Veterinary Directive/Lab Treatment Log, dated 11/18/04, for animal I57114, Study No. (b)(4)

EXHIBIT LIST (Con't)

- Exhibit 19** – Covance “E-Notes”, No. 42052, for Study No. (b)(4)
- Exhibit 20** – Series of emails from Covance Study Director (b)(6), (b)(7)(c) dated November 18 and 19, 2004. (6 pages)
- Exhibit 21** – Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 22** – Covance IACUC Minutes for November 2004. Includes Protocol attached ACUC Review Form for Studies (b)(4) (Amendment 2).
- Exhibit 23** – Covance Request for Veterinary Services, dated 12/22/04, for Animal No. I57523, Study No. (b)(4)
- Exhibit 24** – Covance Request for Veterinary Services, dated 12/22/04, for Animal No. I57527, Study No. (b)(4)
- Exhibit 25** – Covance Request for Veterinary Services, dated 12/22/04, for Animal No. I57528, Study No. (b)(4)
- Exhibit 26** – Covance Individual Clinical Observation records for animals nos. I57523, I57527 and I57528, Study No. (b)(4) (16 pages)
- Exhibit 27** – Covance ACUC Protocol Status Form for Study (b)(4) Final.
- Exhibit 28** – Covance Protocol study No. (b)(4)
- Exhibit 29** – Covance IACUC Minutes for December 2, 2004. Includes attached Protocol ACUC Review Form for Studies (b)(4) (Amendment 2), (b)(4) (Amendment 1).
- Exhibit 30** – Covance Request for Veterinary Services, dated 4/14/05, for Animal No. I57739, Study No. (b)(4)
- Exhibit 31** – Photocopies of two emails from Study Director (b)(6), (b)(7)(c) and one radiograph of animal number I57739.
- Exhibit 32** – Covance Individual Clinical Observation Records for animal no. I57739, study (b)(4) for days 86 – 90.
- Exhibit 33** – Covance Source Animal Data printout for animal I57739, Study (b)(4) days 86 (4/14/05) to 90 (4/18/05).
- Exhibit 34** – Covance Individual Animal Fate Data printout for animal number I57739, Study (b)(4)
- Exhibit 35** – Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 36** – Covance Individual Clinical Observation records for animal I57654, Study (b)(4) (b)(4)
- Exhibit 37** – Covance ACUC Protocol Status Form for Study 6708-107, submitted 2/8/05 by (b)(6), (b)(7)(c)
- Exhibit 38** – Covance ACUC Protocol Status Form for Study 6708-107, submitted 2/17/05 by (b)(6), (b)(7)(c)
- Exhibit 39** – Study No. (b)(4) Protocol, issued by Study Director (b)(6), (b)(7)(c) on 1/14/04.
- Exhibit 40** – Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 41** – Covance IACUC Minutes for June 7, 2004. Includes attached Protocol ACUC Review Form for Study (b)(4)
- Exhibit 42** – Covance Individual Clinical Observation Records for animal no. I56401, study (b)(4)

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- Exhibit 43** – Covance Individual Clinical Observation Records for animal no. I56404, study (b)(4)
- Exhibit 44** – Covance Individual Clinical Observation Records for animal nos. I56417, I56418 and I56419, study (b)(4)
- Exhibit 45** – Series of Veterinary Treatment Logs and Veterinary Requests for animals on Study (b)(4) (14 pages).
- Exhibit 46** – Covance Individual Animal Fate Data for animals on Study (b)(4)
- Exhibit 47** - Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 48** – Covance IACUC Minutes for April 6, 2004.
- Exhibit 49** – Protocol for Study No. (b)(4)
- Exhibit 50** - Covance ACUC Protocol Status Form for Study (b)(4) (Amendment #4).
- Exhibit 51** – (b)(4) PI (Pre Initiation) Meeting Minutes. (Date unknown)
- Exhibit 52** - Notes from a 12/15/04 Pre-Initiation Meeting for Study (b)(4) dated 12/15/05.
- Exhibit 53** – Page 8 from Covance Protocol for Study No. (b)(4)
- Exhibit 54** – Document entitled, “Preclinical and Clinical Safety Assessments for PPAR Agonists”, furnished by (b)(6), (b)(7)(c) Covance.
- Exhibit 55** - Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 56** – Covance (Final) Protocol Status Form for Study (b)(4) (Amendment 2)
- Exhibit 57** – Literature Search for “Continuous Infusion in Dogs, Monkeys performed by (b)(6), (b)(7)(c) (b)(6), (b)(7)(c) Dated May 9, 2001(41 pages)
- Exhibit 58** - Literature Search for “Catheterization 1990 to Present”, with attached email showing it was provided to (b)(6), (b)(7)(c) Covance, on 6/29/05. (9 pages)
- Exhibit 59** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 60** - Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 61** - Covance ACUC Protocol Status Form for Study (b)(4) (Amendment 1).
- Exhibit 62** – Email from (b)(6), (b)(7)(c) to (b)(6), (b)(7)(c) dated 9/3/04.
- Exhibit 63** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 64** – Portion of Covance IACUC Minutes from September 20, 2004. (5 pages)
- Exhibit 65** – Covance Request for Veterinary Services for animal I57607, study (b)(4)
- Exhibit 66** – Covance Veterinary Directive/Lab Treatment Log, for animal I57607, 12/30/04.
- Exhibit 67** – Affidavit of (b)(6), (b)(7)(c) dated 9/13/05.
- Exhibit 68** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 69** – Covance Request for Veterinary Services, dated 10/8/04, for animal I57620, study (b)(4)
- Exhibit 70** – Covance Request for Veterinary Services, dated 12/13/04, for animal I57452, study (b)(4)
- Exhibit 71** – Covance Request for Veterinary Services, dated 2/9/05, for animal I56999, study (b)(4)
- Exhibit 72** – Covance Request for Veterinary Services, dated 2/11/05, for animal I56999, study (b)(4)
- Exhibit 73** – Covance Veterinary Directive/Lab Treatment Log, dated 2/9/05, for animal I56999, Study (b)(4)

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- Exhibit 74** – Covance Physical Examination Form, dated 2/15/05, for animal I56999, study (b)(4)
- Exhibit 75** – Covance Individual Anatomic Pathology Data printout, for animal no. I56999, Study (b)(4)
- Exhibit 76** – Covance Request for Veterinary Services, dated 1/11/05, for animal I56997, study (b)(4)
- Exhibit 77** – Covance Veterinary Directive/Lab Treatment Log, dated 1/11/05, for animal I56997, Study (b)(4)
- Exhibit 78** – Digital photograph of ear for rabbit no. 1277, study (b)(4)
- Exhibit 79** – Digital photograph of ear for rabbit no. 1256, study (b)(4)
- Exhibit 80** – Digital photograph of ear for rabbit no. 1274, study (b)(4)
- Exhibit 81** – Digital photograph of ear for rabbit no. 1274, study (b)(4)
- Exhibit 82** – Individual Clinical Observation records for rabbits on Study (b)(4) (32 pages)
- Exhibit 83** – APHIS Form 7023, Annual Report of Research Facility, for Covance Laboratories Inc., dated 11/16/04.
- Exhibit 84** – Sony Camera CD contains movie files nos. MOV00315.MPG, MOV00320.MPG, MOV00340.MPG, MOV00341.MPG and MOV00342.MPG. Recorded by IES Investigator (b)(6), (b)(7)(c) on 6/10/05.
- Exhibit 85** – Memo from IES Investigator (b)(6), (b)(7)(c) to (b)(6), (b)(7)(c) dated 9/14/05.
- Exhibit 86** – Digital photograph of a canine cage in Building 16, Room 1593, Covance Laboratories Inc. Taken 6/10/05 by IES Investigator (b)(6), (b)(7)(c)
- Exhibit 87** – Digital photograph of a canine cage in Building 16, Room 1593, Covance Laboratories Inc. Taken 6/10/05 by IES Investigator (b)(6), (b)(7)(c)
- Exhibit 88** – Covance Department Operating Procedure, NA-TOPS.213, Methods of Canine Exercise.
- Exhibit 89** - Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 90** – On line room log for study 7049-110 (with attached note from (b)(6), (b)(7)(c) (b)(6), (b)(7)(c) dated 9/4/03 to 9/24/03.
- Exhibit 91(a-c)** Three digital photographs taken of damaged drain area in Bldg. 16, room 1450, Covance Laboratories, Inc. Taken by IES Investigator (b)(6), (b)(7)(c) on 6/10/05.
- Exhibit 92(a-f)** Six digital photographs taken of damaged floor area in Bldg. 16, room 1130, Covance Laboratories, Inc. Taken by IES Investigator (b)(6), (b)(7)(c) on 6/10/05.
- Exhibit 93(a-d)** Four digital photographs taken of inadequate repair of ceiling area in Bldg. 16, room 1480, Covance Laboratories, Inc. Taken by IES Investigator (b)(6), (b)(7)(c) on 6/10/05.
- Exhibit 94(a-c)** Three digital photographs taken of broken restraint tubes found in Bldg. 16, room 1472, Covance Laboratories, Inc. Taken by IES Investigator (b)(6), (b)(7)(c) on 6/10/05.
- Exhibit 95** – Covance Department Operating Procedure, NA-TOPS.222, Methods of Non-Human Primate Socialization and Commingling.
- Exhibit 96** – Covance protocol for Non-Human Primate and Canine Stock/Training Colony, dated 9/28/04.

EXHIBIT LIST (Con't)


- Exhibit 97** – On Line “Comments” document for Project P (b)(4) and P (b)(4) (3 pages total) Received from (b)(6), (b)(7)(c) on 6/20/05.
- Exhibit 98** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 99** – Covance Department Operating Procedure, NA-TOPS.201, General Animal Care and Environmental/Psychological Enrichment-Felines, Canines, Primates, and Swine.
- Exhibit 100** – Covance Pre-Study Physical Exam report for animals on Study (b)(4)
- Exhibit 101(a,b)** – Two Covance Requests for Veterinary Services, for animals Z00666, study (b)(4) and a Guinea pig on study (b)(4)
- Exhibit 102** - Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 103** - Covance ACUC Protocol Status Form for Study (b)(4)
- Exhibit 104** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 105** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 106** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 107** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 108** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 109** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 110** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 111** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 112** – Affidavit of (b)(6), (b)(7)(c) dated 9/8/05.
- Exhibit 113** – Curriculum Vitae for (b)(6), (b)(7)(c) obtained from the employee records files at Covance Laboratories Inc.
- Exhibit 114** – Procedure Certification Record for (b)(6), (b)(7)(c) obtained from the employee records files at Covance Laboratories Inc.
- Exhibit 115** – Operating Instructions Manual for the Eclipse Electrocardiograph machine.
- Exhibit 116** – Article, “Recommendations for Safe Current Limits for Electrocardiographs”, published by the American Heart Assoc., in 1996.
- Exhibit 117** – Affidavit of (b)(6), (b)(7)(c) dated 8/2/05.
- Exhibit 118** – Covance Department Operating Procedure, NA-TOPS.922, Veterinary Examination and Treatment of Animals.
- Exhibit 119** – Covance IACUC Membership, as of May 2005.
- Exhibit 120** – USDA, APHIS, Animal Care, Animal Welfare Complaint, No. 05-024, and attached related documents. (4 pages)
- Exhibit 121** – APHIS Form 7011, Application for Registration, for Covance Laboratories Inc., dated 9/1/03.
- Exhibit 122** - Covance document entitled, “Re: Covance Laboratories Inc. (ID: 507); Reply to Inspection Report Issued on July 14, 2005 to Covance’s Vienna, VA Facility (Site 001, addressed to (b)(6), (b)(7)(c))”

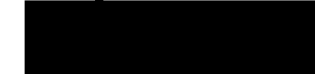
WITNESS LIST

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-----**Veterinary Medical Officer**
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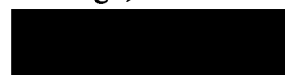
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Mary Beth Sweetland-----**Director of Research & Investigations**
People for the Ethical Treatment of Animals

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