EPA AUDITS VERSION 2.0

Kathy Richards

California Agricultural Research, Inc.

EPA Audit Version 1.0 (Preferred Method 2012, E-mail)

THE NOTICE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of
Enforcement and
Compliance Assurance

SENT BY E-MAIL

July 31, 2012

Michael H. Beevers Ph.D.
California Ag Research, Inc.
4141 N. Vineland Avenue
Kerman, CA 93630

Re: GLP Data Audit Inspection Pursuant to the FIFRA

Dear Dr. Beevers:

The United States Environmental Protection Agency (EPA) has chosen to conduct a data audit of the following studies under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Good Laboratory Practice (GLP) regulations, 40 CFR Part 160.

Study Title	MRID	Lab Project No.
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

The Final Study Reports were submitted to EPA in support of an application for research or marketing permit and indicates that California Agricultural Research, Inc. was the testing facility, and [redacted] were the sponsors for these studies. As the testing facility, EPA is requesting that you submit exact copies of records, reports and data required to maintained by 40 CFR Part 160 and 169.2(k).

The purpose of the data audit is to further examine the Final Report and to determine whether the Final Report complies with the Agency's GLP regulations. Please note that under the GLP regulations at 40 CFR 160.15(b), EPA will not consider reliable for purposes of supporting an application for a research or

marketing permit any data developed by a testing facility or sponsor that refuses to permit inspection. Furthermore, under 40 CFR 160.17(a) EPA may refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with the GLP regulation.

Send all data needed to verify and support the findings in the final report for each study, along with the study protocol (including any protocol deviations and/or amendments) and all reports submitted by your facility to the study sponsors. Raw data needed for this data audit include all information regarding the test system, such as receipt, use and accountability, treatment(s), periodic analysis on the test system, postmortem and histopathology, wet tissues, tissue slides and paraffin blocks (if applicable). Other raw data and records that were not mentioned above, but are necessary for the reconstruction of the study should also be sent. Include the index of Standard Operating Procedures (SOP) in use by the laboratory at the time of study. The EPA inspector assigned to this data audit will identify the SOPs and will request copies. Provide contact information for all personnel associated with the design, conduct, analysis, and reporting of each study identified in this letter. Contact information for each person includes their name, telephone number and e-mail address. Copies of records may be sent in paper format and must be certified as exact copies of the original. A certification form is enclosed.

We request specific information regarding the test substance. Include source and lot number, record of receipt, storage, usage data, test substance inventory logs, and custodial procedures. Requested usage data include evidence of correspondence between test substance received and tested, weights, and preparation of dosages and/or dilutions. In addition, provide a statement from the sponsor indicating the origin of the test substance, namely, if it was sampled from a batch for contemporary commercial use or was synthesized or manufactured for the specific study for which the raw data are being audited. In either case, include along with the statement the supporting chemistry data, i.e., all data to prove the identity and purity of the test substance, the identity of any and all impurities detected by sponsor or manufacturer, and data to establish the storage stability of the test substance during the lifetime of the study.

You may, if you desire, assert a business confidentiality claim covering all or part of the information requested, in the manner described by 40 C.F.R. Section 2.203(b). EPA will disclose information covered by such a claim only to the extent and only by means of the procedures set forth in 40 C.F.R. Part 2, Subpart B. See 41 Fed.Reg. 36902 (September 1, 1976); 43 Fed.Reg. 4000 (December 18, 1985). If no such claim accompanies the information when EPA receives the information, then EPA may make the information available to the public without further notice to you. You should read carefully the above-cited regulations before asserting a business confidentiality claim, since certain categories of information are not properly the subject of such a claim. If you claim information submitted in response to this request as confidential, then also provide a second, redacted copy of the information with all confidential business information deleted.

In addition to this data audit, the inspector will conduct a facility compliance inspection at a later date to determine compliance with the FIFRA GLP regulations at the laboratory. Both the data audit and the

facility compliance inspection are part of the GLP inspection being conducted. The inspector assigned to this data audit will coordinate this facility compliance inspection.

You are requested to provide the Agency with the information and documents identified above within 15 business days of your receipt of this letter by sending them to:

By U.S. Mail:

Daniel Myers
EPA, Office of Compliance
Denver Federal Center
Bldg 25, E2, Box 25227
Denver, CO 80225

By Hand Delivery:

Daniel Myers
EPA, Office of Compliance
Denver Federal Center
Bldg. 25, E3, Room 2246
Denver, CO 80225

Please direct any questions concerning this data audit to Mr. Daniel Myers, EPA, Office of Compliance, GLP Program, at 303-462-9392.

Sincerely,

Francisca E. Liem, Director

Good Laboratory Practice (GLP) Program

Cc: Daniel Myers

CERTIFICATION

I certify under penalty of law that I have personally examined and am familiar with the documents and other information submitted in response to this information request; that based on my inquiry of the persons directly responsible for gathering the information the information is true, accurate and complete; and that all documents submitted herewith are true, accurate and complete. I am aware that there are significant penalties for submitting false information to the United States Government, including the possibility of fine or imprisonment under 18 U.S.C. 1001.

_____

Signature

_____

Name

_____

Title

_____

Company

_____

Date

Steps to Answer Audit Requests

1. Note deadline for data to be received at EPA
2. Make sure sponsor has received audit notification
3. Locate studies to be audited
    1. Conversation as to how sponsor is going to provide their requested data.
4. Decide on format for the data and how you are going to send required data to EPA
    1. Paper Certified Copy
    2. Digital Certified Copy
    3. Reconstructed Notebook with Certified Copy
    4. Certified Copy of Facility Raw Data (if needed).
5. Send off ASAP to EPA
6. And then when advised mark the date on the calendar.
7. Review, review, review.

What was reviewed?

Equipment Logs
Test Substance Receipt, Tracking of Use, and Return/Disposal
COA available (if not, request from sponsor)
SOPs (Organizational Charts, TOC, Historical, etc.)
Archives
Master Schedule
Balances
Facilities and how used.

My Impression of the Audit

Not bad at all