UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 29,1993

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP) Regulations

GLP Regulations Advisory No. 58

FROM: David L. Dull, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Policy & Grants Division of the Office of Compliance Monitoring. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca E. Liem at (703) 308-8333.

Attachment

cc: M. Stahl
C. Musgrove

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

OFFICE OF
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Dear

This is in reply to your request for clarification regarding the responsibilities of the Interregional Research Project No. 4 (IR-4) and pesticide registrants for data developed by IR-4 in support of minor uses. You specifically wanted to know whether responsibility for compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS) applied to the pesticide registrants when IR-4 was sponsoring tests and submitting the final reports to EPA.

As you are aware, any study intended to be submitted in support of an application for a pesticide research or marketing permit must be conducted in accordance with FIFRA GLPS. Among other things, this includes studies in support of tolerance petitions under section 408 of the Federal Food, Drug, and Cosmetic Act. When any such study is submitted, it must be accompanied by a true and accurate statement of compliance or noncompliance of the type described at 40 CFR 160.12 signed by the study director, the study sponsor and the applicant.

If the IR-4 sponsors a study and submits the data to the Agency for the purposes of registration of minor uses or obtaining a related tolerance, the IR-4 assumes responsibility for assuring the compliance status of the study and an authorized representative of the IR-4 must sign the statement of compliance or noncompliance. The study director, who may also be with IR-4, must also sign this statement. It is permissible for one individual to fill both of these functions as long as he or she is clearly identified as such on the statement.

When IR-4 acts as a testing facility and/or sponsor, it is responsible for compliance with GLPS including the provisions for retention of records at 40 CFR 160.195.

In addition-to these requirements, when data are submitted in support of the registration of a particular product, for example, in response to a data call in under FIFRA Section 3(c)(2)(B), the registrant/producer is responsible for maintaining the supporting raw data records pursuant to FIFRA section 8 and the related regulations at 40 CFR 169.2(k). Please note that producers are not required to physically possess such records as long as the location of the records is known, and they can make available the records when requested. -Therefore, as long as such records remain accessible and producers can make them available, they may be

maintained at any location including at IR-4 facilities.

If you have any questions, please give me a call at (202) 260-7824.

/s/ John J. Neyland III, Director
Policy and Grants Division
Office of Compliance Monitoring

cc: Michael M. Stahl (EN-342)
Michael F. Wood (EN-342)
David L. Dull (EN-342W)