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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 5, 1994

MEMORANDUM

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

GLP Regulation Advisory No. 72

FROM: David L. Dull, Acting Director
Agriculture and Ecosystems 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: E. Stanley
E. Schaeffer

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

OFFICE OF
PREVENTION PESTICIDES
AND TOXIC SUBSTANCES

Dear

This is in response to your letter of February 15, 1994, in which your requested clarification regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS). Your question concerned the potential activities performed by the management of a testing facility.

Specifically, you asked whether you, as the owner of a small business, could participate in field projects in the capacity of "technician." You stated that while it would be easiest to hire more people the company size and budget could make this difficult.

Under GLPS, there must be testing facility management as described at 40 CFR 160.31. Further, there must be a study director and quality assurance unit as stated at 40 CFR 160.33 and 40 CFR 160.35, respectively. Th- quality assurance unit (QAU) must be independent of all study personnel.

If the testing facility management personnel who oversee the QAU directly engage in study activities, the QAU cannot be considered to be independent from study personnel. This violates GLPS. Management involvement in studies may trigger other violations as well. For example, if the management personnel who oversee the study director directly engage in the study, this would interfere with the study director's overall responsibility for the technical conduct of the study.

Generally, the GLPS are structured to anticipate that management and study personnel consist of different individuals. As a result compliance issues may arise when individuals who are part of the testing facility management perform study activities. Therefore, although the GLPS do not explicitly state that no management personnel may be involved in study activities, such involvement may lead to violations.

If you have any questions concerning this response, please contact Steve Howie of my staff at (703) 308-8290.

Sincerely yours,

/s/ John J. Neylan III, Director,
Policy and Grants Division
Office of Compliance Monitoring (7202)

cc: David L. Dull
GLP File