OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

GLP Regulation Advisory No. 17

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 Liem at FTS-475-9864.

Attachment

cc: C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dear

This is in response to your letter dated March 24, 1989. concerning FIFRA Good Laboratory Practice (GLP) standards (40 CFR part 160). In that letter you requested clarification of the proposed rule regarding routine laboratory analyses by contracted testing facilities. Specifically, you requested clarification as to whether the existence of a client's internal study officer and Quality assurance unit (QAU) would obviate the need for the duplication of such personnel at contract facilities.

The proposed rule has not yet been published as a final rule. It is not appropriate for our office to issue a formal clarification of the proposed amendments until they are published as a final rule in the Federal Register. Your comments must therefore be addressed in the context of the current rule, which was published in 1983. Our staff has reviewed your comments and offers the following clarification, based on the current rule.

The responsibilities of the study director and QAU include assurance that the performance of a study complies with GLP standards. Their duties include on-site inspection and monitoring of study operations. These activities could be adequately conducted by a client-maintained study director and QAU that are located off-site, if provisions are made to ensure that all required on-site duties are performed.

Compliance with GLPs is a responsibility of the testing facility as well as of the registrant. This is true whether the testing facility is contracted for a portion or for the entirety of the technical effort of a GLP study . The contract testing facility must therefore ensure adequate oversight of study conduct and Quality assurance activities. While adequate standard operating procedures must also be maintained at the contract laboratory, the existence of these would not be sufficient in themselves to ensure GLP compliance.

If you have any questions concerning this response, please contact Steve Howie, of my staff, at (202) 382-7825. Should you require further written clarification of this matter following publication of the final rule amending the FIFRA GLP standards,

please write us again.

Sincerely yours,

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

cc: David Dull