



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES
December 20, 1989

MEMORANDUM

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

GLP Regulations Advisory No. 3

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 FTS 475-9864.

Attachment

cc: C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Dear

This is in response to your letter dated October 19 1989, to David L. Dull. That letter was referred to my office for response. In your letter you requested clarification on the following two points regarding the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs) and the Toxic Substances Control Act (TSCA) GLPs. Your questions concerned the need for quality assurance unit inspections as required at 40 CFR 160.35(b) (FIFRA GLPs) and 40 CFR 792.35(b) (TSCA GLPs). Specifically, you asked whether the preamble discussions to the August 17, 1989 publications of these rules stating that each study must be inspected at least once excluded the possibility of interval inspections are allowed by FDA and how this related to screening pilot and range-finding studies. You also asked what would be considered appropriate to review short-term repetitive studies if random inspection programs are considered inappropriate. We have reviewed your questions and offer the following guidance.

The GLPs state in sections 160.35(b) and 792.35(b) that the QAU "inspect each study at intervals adequate to ensure the integrity of the study". While this does not specify the number or intervals we believe that in any case where a study is not inspected i.e., at least once, there is a clear GLP violation. Our preamble statement concerning random inspections was directed at the concept of allowing random selection of some studies for inspection, instead of inspecting all studies. For the reasons already stated, we do not believe that the regulations allow this.

Finally we do not view range-finding pilot or screening studies as requiring GLP compliance unless they are being performed either as a study or as part of a study (i.e. specified in the protocol of a study) that is to be submitted to EPA. There is no specific regulatory requirement that each pilot, etc., study performed as part of a larger study be inspected by the QAU as long as each larger study is inspected as required. The QAU may find it necessary to inspect some pilot etc. studies to assure the integrity of data from these portions of the studies.

If you have any questions regarding this response please call Steve Howie, of my staff. at (202) 475-7786.

Sincerely yours

/s/Gerald B. Stubbs, Acting Director
Policy and Grants Division
Office of Compliance Monitoring

cc: David Dull