



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

GLP Regulation Advisory No. 16

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 November 21, 1988. In that letter, you requested a reply concerning the need for reserve sample retention requirements under 40 CFR 16g.105(d), assuming the nature of the study is chemical analysis. Specifically, you asked about the effect on compliance of factors that cause actual study duration to differ from the originally planned duration.

Neither the 1983 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice (GLP) standards nor the 1987 proposed revisions suggest that study duration is anything but the actual time that the study takes. If a study is of more than 4 weeks actual duration, it would be required to have reserve samples taken under 40 CFR 160.105(d) provided the type of test is subject to that section. Unforeseen circumstances that increase the length of time that a study takes may affect whether a reserve sample is needed.

The requirement is for a reserve sample to be retained from each batch of test and control substance. A retention sample need not be taken from each subquantity supplied to the testing facility for each study. It may be taken from different subquantity of the same batch, and taken after the beginning of a study, as long as it is retained for the period of time provided in 40 CFR 160.195.

If you need clarification or have other question concerning this requirement, please call Steve Howie of my staff at (202) 382-7825.

Sincerely,
/s/ John J. Neylan III, Director