UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

November 7, 1990

MEMORANDUM

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

GLP Regulations Advisory No. 23

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-398-8265 or (703) 308-8265.

Attachment

cc: C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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Dear

This is in response to your letter of April 10, 1990, requesting clarification of certain requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPs). Specifically, you asked whether the requirements stated at 40 CFR 160.105(e) require that analyses be performed during a study to verify stability of the test, control, or reference substances under storage conditions at the test site, or, alternatively, whether stability studies performed prior to the study could obviate the need for such additional analyses.

The GLPs state at 40 CFR 160.105(e) that the stability of test, control, and reference substances under storage conditions at the test site must be known for all studies. In a situation where stability testing has been previously performed under GLPs and such testing demonstrates stability under the storage conditions at the test site (i.e.,comparable duration, temperature, etc.) then it is not necessary to retest for stability to comply with GLPs.

Where the stability is determined prior to the study under certain conditions, it is necessary to know that those conditions apply to the study in question. If such conditions are not known, or if stability data are otherwise insufficient, (e.g.,not done under GLPs), it is necessary to reaffirm by either completing stability testing under GLPs before the start of the study, or concomitant testing during the study.

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

Sincerely yours,

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

cc: David L. Dull
GLPS File