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. 10

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 of February 9, 1990, to David L. Dull of the Laboratory Data Integrity Assurance Division. In your letter you requested clarification concerning the application of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice (GLP) standards during the preparation and transmission of test substances to be used In studies performed under GLP's.

The FIFRA GLP standards are intended to provide assurance that laboratory conduct during the performance of studies to be submitted to EPA is such that it does not jeopardize the integrity of the data generated. At 40 CFR 160.105, the GLPs specify that there must be determinations of the identity, purity strength, composition, or other appropriate characteristics of test, control, or reference substance before its use in a study. Since these determinations must be made in the direct context of the use of the material ln the study, they are part of study performance and must comply with GLPs. Further there are provisions at 40 CFR 160.107 that procedures assuring proper storage, distribution, Identification and receipt of the test control and reference substances be followed. This includes handling during and after the time that the substance Is characterized.

However the methods of synthesis, fabrication or derivation of the test control or reference substance need only be documented before the start of the study and the location of documentation specified. The actual synthesis, fabrication or derivation need not be performed under GLPs.

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
GLP File