UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 24,1992

MEMORANDUM

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

GLP Regulations Advisory No. 54

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 (703) 308-8333.

Attachment

cc: M. Stahl
C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
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AND TOXIC SUBSTANCES

Dear

This is in reply to your letter of July 24, 1992, in which you requested clarification regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS) requirements. Specifically, you wrote to ask whether archiving requirements apply to analytical standards used in GLPS. If so, you wanted to know whether a single aliquot of the pure material or, alternatively whether an aliquot of each preparation would need to be kept. Your question was prompted by question number 18 of the May 12, 1992 FIFRA GLP Questions and Answers (Q&A) document which stated that analytical standards are considered to be reference materials under GLPS.

As stated in the May 12 Q&A document, analytical standards are considered to be reference substances. As such, all GLP standards that apply to reference substances apply to the analytical standards. Therefore, as stated at 40 CFR 160.105(d), if a study is of greater than four weeks experimental duration, a reserve sample must be maintained for the duration of time provided at 40 CFR 160.195.

This requirement applies to the pure analytical standard that is used in the study. If more than one batch of standard is used, a reserve sample of each batch must be kept. A single reserve sample (of each batch) would ordinarily be adequate. It is not necessary to keep samples of preparations made using the standard.

If you have any questions concerning this response, please contact Steve Howie of my staff at (703) 308-8290.

Sincerely yours,

/s/John Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring (EN-342)