MEMORANDUM

December 20, 1989

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

GLP Regulations Advisory No. 7

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
Dear

This is in response to your letter of March 14, 1990, to Dr. David L. Dull requesting clarification of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice standards (GLPs) requirements involving field dissipation studies. Specifically, you asked how long soil, water, and plant samples analyzed for pesticide content as part of these studies need to be retained.

The GLPs state at 40 CFR 160.190(a) that specimens of soil, water, and plants do not need to be retained after quality assurance verification. The preamble to the rule published on August 17, 1989 (54 FR 34052) states that this means that such samples shall be retained until the quality assurance unit assures that their discarding does not negatively impact the integrity of the study. Unless such assurance is provided, such samples must be retained for the period of time specified under 40 CFR 160.195.

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