UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

August 10, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 50

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: M. Stahl
C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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Dear

This is in reply to your letter of April 13, 1992. In that letter you requested clarification regarding the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS).

You were specifically interested in the sample retention requirements for certain test substances used in studies performed under GLPS. The test substances in question are various fungal and bacterial cultures which, according to your letter, are relatively fragile. You asked whether it would be permissible to dispose of such samples after quality assurance verification as provided at 40 CFR 160.195(c), or whether it would instead be necessary to first obtain notification from EPA as provided at 40 CFR 160.195(h).

The provisions of 40 CFR 160.195(c) apply to those types of non-documentary materials which the EPA believes can be disposed of without significant harm to the integrity of the study. As stated in this subsection, certain materials (i.e., wet specimens, samples of test substances, etc., which are relatively fragile and differ markedly in stability and quality during storage) need be retained only as long as the quality of the preparation affords evaluation. Other materials (i.e., specimens obtained from mutagenicity tests, etc.) may be disposed of at any time after quality assurance verification.

The provisions of 40 CFR 160.195(h) are intended to provide a means for disposal of certain materials which are not covered by 40 CFR 160.l95©. Thus, materials which are covered by the provisions of 40 CPR 160.195© do not need to meet the Agency notification provisions of 40 CFR 160.195(h) before they are discarded.

The bacterial and fungal culture material that you describe may be of a nature that would allow disposal under the provisions of 40 CFR 160.195(c). For this to be the case it is necessary to document that the material is relatively fragile and otherwise does not afford evaluation. Without such documentation the provisions

of 40 CFR 160.195(h), requiring EPA notification would apply. Assuming that such documentation exists, and that quality assurance verification is obtained prior to sample disposal, there is no need for EPA notification prior to disposal.

In the case that materials are discarded under the provisions of either 40 CFR 160.195(c) or (h), documentation relevant to the disposal of such samples must be retained for the duration of time applicable to sample retention at 40 CFR 160.195(b). Such records must identify the discarded material and provide the required support for any decisions regarding sample disposal. Finally, please note that all other applicable federal, state, and local regulations governing waste disposal must be complied with when any materials are discarded.

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

Sincerely yours,

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

cc: David L. Dull
GLP File