UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

May 5, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 44

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 March 2, 1992 to Dr. David Dull of the Laboratory Data Integrity Assurance Division. Your letter was referred to my office for response.

You requested information regarding compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS). Specifically, you requested information regarding acceptable practices for archiving of raw data under GLPS and the circumstances under which copies can be used.

Your practices include recording data from several studies in one bound notebook. At the completion of each study you photocopy and stamp as true copies the data for that study and transfer the copies to archives. You then continue to use the' notebook for additional studies until it is full, at which point it too is archived.

You asked whether these practices comply with GLPS, since you had heard that copies can only be used to replace data on non-permanent media such as decomposing or light sensitive paper, or to provide back-up for audit purposes. You had also heard that the GLP archiving requirements referred to original data, and that photocopies could not be used to meet the need to archive data at or before the completion of each study.

At 40 CFR 160.3 the GLPS provide that "In the event that exact transcripts of raw data have been prepared...tho exact copy...may be substituted for the original source as raw data." Further, the GLPS provide, at 40 CFR 160.195 (I) retention of records ], that records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

Clearly, there are provisions within the GLPS tor the substitution of true copies for original records. These provisions allow for the use of such copies to meet GLP archiving requirements Thus, archiving of "true copies" complies with GLPS as long as the true copies are placed in archives before or immediately at the time the study report is signed by the study director. However, the "true copy" provisions under GLPS are limited entirely to GLP compliance and do not extend to regulatory requirements elsewhere in FIFRA. specifically, the FIFRA section 8 (books and records) regulations at 40 CFR 169 2(k) require retention of all raw data,

such as original laboratory notebook These requirements are met by your procedure of archiving the original laboratory notebooks (from which true copies have been archived for GLP purposes) after the completion of several studies per notebook.

In summary, the procedures which you described appear to be adequate to meet the separate requirements of GLPS and FIFRA section 8. 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, Director,
Policy and Grants Division
Office of Compliance Monitoring (EN-342)

cc: David Dull
GLP File