UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

June 28, 1991

MEMORANDUM

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

GLP Regulations Advisory No. 35

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 398-8333 (703) 308-8333.

Attachment

cc: C. Musgrove

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dear

This is in response to your letter of March 20, 1990, to David Dull in which you raised questions on EPA's policy regarding retention of raw data as required under section 8 of the Federal Insecticide Fungicide, Rodenticide Act (FIFRA). Specifically, you addressed the regulatory requirements for the retention of all underlying raw data at 40 CFR 169.2(k) and the Good Laboratory Practice standards (GLPs) definition of "raw data" at 40 CFR 160.3 and records retention requirement at 40 CFR 160.195(i).

It was your contention that these requirements do not conflict since: (1) FIFRA section 8(a) provides that the Administrator may prescribe regulations requiring retention of records; (2) although registrants are required at 40 CFR 169.2(k) to retain all underlying raw data, the term "raw data" is not therein defined; (3) "raw data is defined in the GLPs at 40 CFR 160.3 which provides that "exact copies" of transcripts of raw data may be substituted for original raw data; and (4) it is stated further under GLPs at 40 CFR 160.195(i), that records "required by this part may be ...true copies..."; that it is permissible for persons to substitute exact copies for original records to meet all regulatory needs for raw data retention. You further state that, since the term "exact copy" is not in itself defined, companies must set their own policy regarding what constitutes an "exact copy" and be prepared to defend it.

Please note that GLPs include specific archiving requirements for raw data, e.g. indexing for retrieval, minimization of deterioration, protected access, etc. Certain procedures may not be practicable with original records. For example, heat sensitive papers may deteriorate with time, while oversized Printes en c9cyo charts and tape-recorded voice records may be difficult to index for expedient retrieval. After copies are made to assure compliance with GLP archiving requirements, the original records must still be retained to assure compliance with 40 CFR 169.2(k).

We agree that there is no conflict between GLPs and FIFRA section 8 regulations. However, GLPs must not be viewed as superseding the records retention requirements stated at 40 CFR169.2(k), or of providing regulatory clarification of terminology used in 40 CFR 169.2(k). Consequently, compliance with GLPs may be accomplished through retention of copies of raw data,

but the destruction of original records would still be a violation of theprovisions stated at 40 CFR 169.2(k).

I hope this answers your questions. If you have further questions 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

cc: David Dull, EN-342
GLP file