UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 7,1993

MEMORANDUM

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

GLP Regulations Advisory No. 57

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
PREVENTION, PESTICIDES
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Dear

This letter is in reply to a question that you asked at the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS) Conference which our Office held in Arlington, Virginia on September 9 and 10 of this year. Your question dealt with the issue of raw data retention requirements under Section 8 of FIFRA.

Specifically, you wanted to know whether underlying raw data for a study is required to be maintained after the performance of a new study which supersedes it. This situation could arise if new research is performed to determine a pesticide active ingredient's effects. In the case that the old study' B results are no longer used in Agency decision making, you wanted to know whether it is still necessary to retain the raw data which support that study.

As stated at 40 CFR 169.2(k), in the regulation titled "Books and Records for Pesticide Producers and Distributors," pesticide producers are required to maintain records of all underlying raw data from research relating to registered pesticide. This requirement is not limited to data which was actively being used for regulatory decision making, and, hence, does apply to studies which have been superseded. Such research may still contain valuable information, and discarding the underlying raw data would compromise the integrity of the research findings. Hence, underlying raw data for older, superseded studies must still be maintained.

The FIFRA Section 8 regulations state that these records, as with any other research data, must be maintained for as long as the pesticide is registered and the producer is in business. It is unlawful for the producer to discard raw data related to a registered pesticide within this time period.

Please note that GLPS may require data retention for periods of time exceeding the period of time stated at 40 CFR 169.2(k). In order to comply with the GLP data retention requirements at 40 CFR 160.195 (b) raw data must be retained for whichever period of time is longest: (l) the period during which the sponsor holds the research or marketing permit (i.e., registration) to which the study is pertinent; (2) five years following the date the data are submitted to EPA; or (3) in cases where the data are not submitted, 2 years following the date the study was completed, discontinued, or terminated. As with data retention requirements stated at 40 CFR 169.2(k), these requirements are not affected by the performance of

additional studies.

If you have any questions concerning this response, 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