UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

December 20,1989

MEMORANDUM

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

GLP Regulations Advisory No. 4

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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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Dear

This is in response to your letter, dated October 19, 1989, to David L. Dull. This letter was referred to my office for response. In that letter, you requested clarification on the following issues related to Good Laboratory Practice standards (GLPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) at 40 CFR Part 160. I have listed your questions and followed each by a response.

1. Does GLP cover only the quality and integrity of study data generated and not the science of the study?

Response: GLPs are primarily intended to ensure data quality and integrity. Insofar as scientific methodologies affect this, e.g., instrument calibration, test article characterization, etc., they are subject to the GLPs. Also, a GLP violation would occur if a protocol was not followed. Please note that EPA has regulations and guidelines besides GLPs which determine what studies are required and how such studies are to be conducted.

2. In relation to multiple study locations, can a study director be designated for individual locations? Also, can a single study director be designated for multiple locations?

Response: The GLPs state at section 160.33 that the study director represents the single point of study control. The GLPs also define the term study as an experiment conducted "at one or more locations." We interpret this as meaning that no more than one study director shall be assigned to a given study, and that study director may, by definition, be responsible for more than one location of experimental work. Testing facility management is still responsible to assure that adequate personnel are available at all locations; as stated at section 160.31(e).

3. When contracting field residue studies, can the sponsor define the contractor's location as a facility?

Response: The GLPs define the testing facility as "the person who actually conducts the study". This includes a contractor who performs the experimental work involved in the study. Please note that the term "testing facility" will include more than one

physical location, if the study is performed at multiple locations. It will also include more than one organizational unit if more than one organizational unit is involved in the study's conduct.

4. Will it be necessary to submit copies of individual field trial notebooks as part of a multiple trial data submission, or may summaries of raw data on test conditions for each location be submitted?

Response: Under GLPs, a summary and analysis of the raw data are required in the study report (section 160.185(a)(11)), but not a complete copy of raw data. Program-specific guidelines that indicate a need for submission of raw data should be referenced to determine whether a copy of raw data, i.e. field records, is required in the report. In any case, the original raw data would need to be archived at the completion of the study, and the location of the archives listed in the final report.

If you have questions concerning this response; please contact Steve Howie of my staff at (202) 475-7786.

Sincerely yours,

/s/Gerald B. Stubbs, Acting Director
Policy and Grants Division
Office of Compliance Monitoring

cc: David L. Dull