



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

January 13, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 39

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 May 21, 1991, to David L. Dull regarding Good Laboratory Practice Standards (GLPS). That letter was referred to me for reply. Although not specifically described, it is assumed that you are interested in an interpretation regarding the GLPS regulations promulgated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

In your letter you asked whether your facility would be in compliance with GLPS when using a generic protocol system. Specifically, a generic protocol describing certain requirements common to similar studies would be transmitted to a sponsor for review and approval. The approved generic protocol would be transmitted back to your facility and copies would be maintained at both your facility and the sponsor's facility. For each specific study, a letter of authorization would be additionally obtained from the sponsor. The letter of authorization references the generic protocol, the study name, and the test substance. Presumably the authorization letter will include the proposed experimental start and termination dates, and any other protocol requirements not covered by the generic protocol.

The type of approach described above could be an acceptable mechanism to obtain sponsor approval of the study-specific protocol, as is required at 40 CFR 160.120(a)(14). Note that a study protocol must still be drafted for each study which is signed by the study director. That study protocol would be considered "approved" by the sponsor if and only if it contains just those elements contained in the approved generic protocol and the letter of authorization. It may contain such elements by referencing the appropriate approved documents, but only if the documents are themselves maintained and available and the references are clear and unambiguous. If there are any elements included in the study protocol which are either not stated in, are altered from, or are in addition to the elements contained in the approved generic protocol and/or the letter of authorization, these changes must be additionally approved by the sponsor and the date(s) of approval maintained with the protocol.

Records of the approval of the generic protocol and the letter of authorization, as well as records of all approved changes or revisions to the protocol must be maintained with the study protocol and signed and dated by the study director. It is presumed that instructions from the sponsor to alter an existing

protocol constituted approval of protocol changes.

If you have any questions on 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

cc: David L. Dull
GLP file