



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

April 6, 1994

MEMORANDUM

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

GLP Regulations Advisory No. 70

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) 308-8333.

Attachment

cc: M. Stahl
C. Musgrove



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

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Dear

This is in response to your letter of February 4 1994 in which you requested guidance with respect to Federal Insecticide Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS). The area in which you requested guidance dealt with final reporting needs for tests terminated as invalid.

You described a scenario involving a test performed at a contract facility where preliminary evaluations indicated that the test was invalid because of various technical and scientific problems, e.g., too small a number of test animals. The client requested that the test be repeated under an enhanced test design and does not wish that resources be spent writing a detailed final report for the invalid test. The client has instead proposed that an abbreviated report be prepared and filed with the raw data. However, the testing facility quality assurance administrator has objected to this procedure and contends that a detailed report must be filed for the invalid test. Your request specifically addressed whether an abbreviated report could be prepared for the invalid test or whether full reporting is required.

You are advised that if the termination of a test believed to be invalid constitutes termination of a GLP study the full reporting requirements stated at 40 CFR 160.185 apply. However, if the study itself is not terminated and additional testing is performed under the study protocol it may not be necessary to prepare a separate full report complying with all standards at 40 CFR 160.185 for the first test.

In the latter case, the aborted test would be part of the same study as the retest, and a single final report covering both tests and complying with all requirements at 40 CFR 160.185 must be prepared. In this situation the study protocol must be amended prior to retesting unless the protocol already provides for such retesting. The amendment must provide for any changes in experimental design proposed experimental start and termination dates, and any other aspects of the study affected by the performance of the retest. Standard operating procedures, as appropriate to such circumstances, must also be followed. Since the terminated test would be part of the same study as the retest, all documentation, data, specimens, and other records pertinent to the terminated test would be subject to the same retention requirements as apply to the retest. Please note that records of the terminated test must be maintained even if that test is treated as a separate

study. Refer to 40 CFR 160.195 and 40 CFR 169.2(k) to determine the applicable record keeping requirements under GLPS and FIFRA section 8, respectively.

Finally, you are reminded that even when a test is terminated for scientific or technical reasons, test results indicating unreasonable adverse effects of a registered pesticide are subject to reporting requirements under FIFRA section 6(a)(2). Please refer to 40 CFR Part 153 Subpart D for further clarification of these reporting needs.

In summary, you may either terminate and prepare a final study report for a flawed test, or retest under the same study protocol, amended as necessary, and cover both the aborted test and the retest under the same final report. In either case, record keeping and reporting requirements apply to the terminated test.

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 III, Director,
Policy and Grants Division
Office of Compliance Monitoring(EN-342)

cc: David L. Dull
GLP File