



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

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

December 18, 1997

MEMORANDUM

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

GLP Regulations Advisory No. 79

FROM: Rick Colbert, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Agriculture and Ecosystems Division of the Office of Compliance. 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 (202) 564-2365.

Attachment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Dear

This is in response to your letter of October 1, 1997, requesting clarification on an issue related to whether a Good Laboratory Practice Standards (GLPS) compliance statement is necessary for interim studies. In particular, you were concerned that finished studies will have two compliance pages associated with the study which may contradict each other.

40 CFR Part 160.12 requires that studies submitted to the Agency in connection with an application for registration of a pesticide include a signed compliance statement. This would include interim reports that are submitted to the Agency. As long as the compliance statement clearly states the reasons why the study is not in compliance with the GLPS, the Agency can evaluate whether to accept or reject the study. If, for instance, the testing facility has not conducted an audit of the study because the audit is scheduled for a later time, the compliance statement should reflect that fact. The Agency is aware that this may result in conflicting compliance statements and that such situations are an inevitable result of interim reporting prior to the completion of the study.

If I can be of any further service, please do not hesitate to contact me or David Stangel of my staff at 202-564-4162.

Sincerely yours,

Richard Colbert, Director
Agriculture and Ecosystems Division