UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 24,1992

MEMORANDUM

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

GLP Regulations Advisory No. 53

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
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AND TOXIC SUBSTANCES

Dear

This is in response to your letter of September 3, 1992 in which you asked for clarification regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS). Specifically, you wished to know if the requirement that the final report be signed and dated by the study director (40 CFR 160.185(b)) means that the study director's signature must be personally dated. You asked whether this standard could instead be met by including a printed date on the cover page of the study final report.

Since the GLPS do not explicitly state how the report be dated, mechanical means of dating are acceptable. This could include, as you suggested, a dated cover page for the study final report, provided that is the date that the study director actually signed the report. Please note that the date that the study director signs the final report is defined in the regulations as the study completion date (40 CFR 160.3). If the cover page date is not the date the report was signed, and the signature itself is not dated, this would be a violation of the GLPS.

Therefore, you are advised that, while various means of dating the final report may be used, problems arise if the actual date that the study director signs the report is not indicated. It would appear that the simplest way to assure compliance with this provision would be for the study director to personally date his or her signature.

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)