UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

June 22, 1992

MEMORANDUM

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

GLP Regulations Advisory No. 49

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) 308-8265.

Attachment

cc: M. Stahl
C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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Dear

This is in reply to your letter of April 7, 1992 in which you requested clarification regarding certain studies being performed by N currently and in the near future. Your questions had to do with drafting protocols and reporting study results when there are two different active ingredients which are co-applied in field dissipation studies.

Specifically, you stated that N was contracted by two task forces, the Pyrethrum Joint Venture and the Piperonyl Butoxide Task Force II to conduct field dissipation and plant residue trials for the active ingredients pyrethrum and piperonyl butoxide. At that request of your clients the two actives were applied as a single formulation, but the two task forces have each requested that the other task force not receive its data. You stated that you believed that since that two actives were co-applied for each trial under a single protocol, that a single study report should be written to encompass the results concerning both actives. However, to suit your clients needs, it would not be acceptable to submit a single report covering both actives to each of your clients.

You proposed separating the data to protect the sensitive information for each active, i.e., the analytical data for each active, from disclosure to the client concerned with tho other active ingredient. To enable you to do this, your clients agreed to a reporting format involving three volumes: Volume 1 would involve field data results common to both studies; Volume 2 would involve analytical data results resources involving piperonyl butoxide; and Volume 3 would involve analytical data results involving pyrethrum. EPA would receive all three volumes while the Pyrethrum Joint Venture would receive Volumes 1 and 3 and the Piperonyl Butoxide Task Force II would receive Volumes 1 and 2. As described in your letter, all of the work involving both active ingredients (combined for application in a single formulation) would bo considered a single study and would be submitted to EPA as such.

You clarified several points in a discussion with Steve Howie, of my staff on May 5, 1992. In that conversation you stated that this format would be used initially for the field dissipation trial and repeated separately (i.e., three additional volumes) for the plant residue trial. You also stated that it was the intent of the

Piperonyl Butoxide Task Force II and the Pyrethrum Joint Venture to be represented by a single sponsor in supporting each study concerning both actives. You also stated that it was your understanding that the co-application of these actives with the subsequent reporting of results concerning both actives in combined study reports (i.e., one field dissipation study and report for both actives, and one plant residue study and report for both actives) was the technical approach preferred by the EPA program office which would be reviewing the data.

The two potential areas of conflict between the GLP regulations and your plan for study administration lie in (1) definition of work involving two actives as a single study under the definition provided in the GLP regulations and (2) assuring that study sponsor responsibilities are properly executed. Our office has reviewed your plan and, contingent on your meeting those two concerns, sees no conflict with performing this study in full compliance with GLPS.

The plan for including experimental work involving two actives within a single study appears to be sound in this case since the two actives (one is a synergist for the other) are normally marketed for co-application, and data regarding their characteristics when they are co-applied are needed for Agency decision making. The alternative of drafting separate study documentation in order to identify a separate “study” for each active would be unnecessarily duplicative. Hence, the performance of this work under a single study protocol for each experiment covering both actives (one protocol for the combined field dissipation test and one protocol for that combined plant residue test} is acceptable.

The plan of identifying a single sponsor with overall responsibility for the study would be in accordance with the GLPS provided that this person complies with, the definition of sponsor as provided at 40 CFR 160.3, i.e., such person “(1)... initiates or supports [the study], by provision of financial or other resources; (2) ...submits [tho] study to EPA in support of an application for a research or marketing permit; or (3) [is the] testing facility, if it both initiates and actually conducts the study." Also, this person must perform all sponsor related activities under GLPS including approving that protocol (40 CFR 160.120(a)(14)), signing the study compliance statement (40 CFR 160.12), and maintaining a copy of the final report (40 CFR 160.185(d)).

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 (EN-342W)
Allan S. Abramson (H7502C)
Anne E. Lindsay (H7SOSC)
GLP File