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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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July 30, 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT : Laboratory Data Audit. Stauffer Chemical Co. Environmental Health Center; Farmington, CT. February 19-22, 1985.

FROM : Roland A. Gessert, D.V.M.; Veterinary Medical Officer/Toxicologist

TO : John A. McCann, Director; National Laboratory Audit Program

Roland A. Gessert

This report provides information previously provided to the Inspector at the inspection site. While at the laboratory we ascertained that Stauffer's acute studies were conducted at their Richmond, California laboratory. Multiple dosing and inhalation toxicity studies are conducted at the Farmington, CT facility.

While we were at the laboratory, Stauffer was acquired by Chesebrough Foods Co.

All the studies scheduled for audit were audited. These included:

- Ro-Nset 2-year oral toxicity study in rats
- R-29148 2-year chronic toxicity/oncogenicity study in rats
- R-40244 (Racer 2-E) multi-generation reproduction study in rats
- MU-678 Teratogenicity study in New Zealand rabbits
- SC-0224 Teratogenicity study in CD rats

In the initial 2-year rat study with Ro-Nset, a NOEL was not demonstrated, peripheral neuropathy being demonstrated at all doses. (Hazleton Study 132-134, Accession # 240914). Therefore, Stauffer conducted a repeat 2-year rat study # T-10114. In the repeat study a neuropathy NOEL was demonstrated at 10 ppm and a myopathy NOEL at 60 ppm. The repeat study was Core graded Supplementary because histopathology was not done. However, these two studies combined can be graded Core Minimum or Core Guidelines. (In the one-liners, the Hazleton study is graded Core Guidelines.)

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In the multigeneration reproduction study of Racer 2-E (P 0-24) rats, we inquired why there was no sperm analyses for P₂ males. It is not required. Only data for 2 generations are now required, and were provided. In this study we compared testes/epidymides weights and lesions with histopathology at the high dose. Everything check O.K.

The teratogenicity study of SC-0224 in CD rats which I had reviewed, I had declared Core Supplementary data because it was not clearly stated whether doses administered were based on the 19.2% material or on the active ingredient. The data audit verified that doses were based on the active ingredient. The data for this study now are Core Minimum.

Dr. M. Adrian Gross and I worked together in auditing the Stauffer studies. Therefore, our reports should be combined for a complete audit report.



Roland A. Gessert, D.V.M.