UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

FEB 24 1987

MEMORANDUM

SUBJECT: EPA REg. No. 359-686. Lindane: Amendment to the protocol for the rat chronic feeding/oncogenicity study concerning the 30 day sampling time for blood, urine and clinical chemistries (Life Science Research protocol prepared October, 1986).

TOX. CHEM. No. 527
TOX. PROJECT No. 7-0183
Record No.: 185398

FROM: John Doherty
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TO: George LaRocca
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THRU: Edwin Budd
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THRU: Theodore Farber
Chief
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Dr. Glenn Simon on behalf of the Centre International d'Etudes du Lindane (CIEL) has enquired via a telephone call to Dr. Farber and Ed Budd concerning the frequency of sampling the blood and urine in the protocol for the rat oncogenicity/ chronic feeding (2 year) study.

In the Toxicology Branch review of the protocol for this study (refer to J. Doherty memo dated December 24, 1986 for EPA Reg. No. 359-666), it was requested that an additional sampling time at 30 days be included for assessment of the

blood elements, urinalyses and clinical chemistries to assess for possible early transitory effects of lindane. The protocol for this study (as prepared in October, 1986) schedules the first assessment for these parameters at 6 weeks.

Dr. Simon has objected that 30 day and six week sacrifice times are too close together to justify the expense and extra time and resources.

As per discussion with Dr. Louis Kasza (TB staff pathologist January 21, 1987) TB has agreed that the protocol may be changed as follows:

change the 6 week interim sacrifice and bleeding to 4 week interim sacrifice and bleeding

eliminate the 6 weeks interim sacrifice and bleeding.

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