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

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Subject: I.D. No. 080801-000100: Ametryn. Neurotoxicity Data Waiver Request

Tox. Chem. No. 431
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CONCLUSION

The waiver request submitted by Ciba-Geigy regarding the Agency's neurotoxicity testing requirements should be granted at this time. However, neurotoxicity testing may be required in the future, should the Agency's testing requirements change.

ACTION REQUESTED

Toxicology Branch I was asked to review the waiver request for neurotoxicity testing (Guidelines 81-8-SS and 82-7-SS) of Ametryn, submitted by Ciba-Geigy Corporation under Phase 4 Data Call-in 90-day response.

COMMENT

Concern had been raised for potential Ametryn neurotoxicity based on effects seen in moribund rats during an acute oral study. Ciba Geigy had countered that the effects observed were not due to primary neurotoxicity, but were artifacts of the moribund condition of the animals.

After reviewing data summaries from chronic (dog) and chronic/onco (rat) studies, and examining the data from an oncogenicity (mouse) study, all of which failed to show primary neurotoxicity, and conferring with neurotoxicologist William Sette of the Science Advisory Branch, HED, it is concluded that the waiver request is justified, and should be granted. This decision was confirmed by the HED FIFRA '88 committee on Nov. 19, 1992.

Neurotoxicity testing may be required in the future, should the Agency's testing requirements change.