information on adverse reactions, drug interactions, and management of overdosage. A warning against use of the products during pregnancy was also added because of the danger of causing addiction in the fetus and producing a neonatal withdrawal syndrome.

RECENT DEVELOPMENTS AND ACTIONS

On November 22, 1978, the Secretary of the Department of Health, Education, and Welfare was petitioned by the Health Research Group (HRG) to suspend approval of the NDA's for propoxyphene-containing products under section 505(e) of the Federal Food, Drug, and Cosmetic Act on the grounds that the continued marketing of these drugs represent an imminent hazard to the public health. HRG requested alternatively that if the Secretary did not suspend, he support HRG's petition to DEA that propoxyphene be rescheduled as a Schedule II narcotic under the Controlled Substances Act.

FDA's Bureau of Drugs is conducting a new review of all data bearing on the safety and effectiveness of propoxyphene including those studies referenced in the HRG petition.