REGULATORY ACTIONS

Over the years, in response to problems associated with efficacy and safety of propoxyphene products, FDA has taken a number of actions:

-- In 1972, because of misleading statements on the effectiveness of Darvon made to physicians in a letter from Eli Lilly and Company, we required the manufacturer to issue a "Dear Doctor" letter stating: "There is no substantial evidence to demonstrate that 65 mg of Darvon is more effective than 650 mg of aspirin (two 5-grain tablets), and the preponderance of evidence indicates that it may be somewhat less effective."

-- In April 1976, FDA's Controlled Substances Advisory Committee (CSAC) recommended that propoxyphene (and its salts and preparations) be controlled in Schedule IV of the CSA.

-- DEA, in March 1977, placed propoxyphene, its salts and preparations, in Schedule IV of the Controlled Substances Act.

-- Labeling for propoxyphene was further revised in 1978 to add a warning against the additive depressant effect of the products when used in conjunction with alcohol, tranquilizers, sedative hypnotics, and other central nervous system depressants, and to require additional