Secretary for Health, who has delegated authority to make drug scheduling recommendations on behalf of the Department, will make a recommendation to the Department of Justice on propoxyphene in the near future, after consideration by FDA and its Drug Abuse Advisory Committee.

Second, FDA will expeditiously prepare and distribute appropriate information for physicians, dentists, and pharmacists regarding the risks associated with the use of propoxyphene. This information will encourage physicians and dentists to reconsider the risks of and need for the drug in specific cases. It should also help deal with the problems of suicide and accidental deaths from drug interactions by making physicians and dentists more cautious in prescribing the drug for patients who may be suicidal or who may be using alcohol or other drugs affecting the central nervous system. This information will also encourage pharmacists, when dispensing propoxyphene, to put on the container warnings against taking the drug in combination with tranquilizers or alcohol.

Third, FDA will promptly prepare and distribute appropriate information for the general public, in the form of a published article or otherwise, regarding the risks associated with the use of propoxyphene.

Although I believe these actions will help protect the public, I do not believe that the completion and evaluation of these actions are necessary before a decision on the suspension or withdrawal of the propoxyphene NDA's can be made.

VI. Conclusion

At this time, I do not believe that there is sufficient evidence available showing that the continued use of propoxyphene constitutes so serious a threat to public health as to warrant the extraordinary action of summary suspension of general distribution of the drug, pending initiation and completion of the procedures to determine whether propoxyphene should be removed permanently from the general market. Based on the record currently before me, I am unable to declare propoxyphene an "imminent hazard."

The Act carefully balances the safeguards against improvident withdrawals of NDA's and the need to protect the public health from significant risks. The suspension power vested in the Secretary should be used sparingly, when it is likely that the drug will ultimately be withdrawn from the market and immediate action will prevent serious harm during the pendancy of the withdrawal proceedings. The issues in the case of propoxyphene are in significant doubt, and I am not prepared to predict their outcome at this time.

The fact that I am not granting the HRG petition at this time does not mean that further evidence cannot lead me to an opposite conclusion. If, in the course of FDA's further review of propoxyphene, new information is developed to show that propoxyphene meets the criteria for suspension, I will act promptly. Furthermore, the other steps that I have directed should reduce the risks that propoxyphene poses to the public health, while FDA holds its hearing to determine whether the drug should be removed from the market.

Dated February 15, 1979.

JOSEPH A. CALIFANO, Jr.,
Secretary of Health, Education, and Welfare.

[From the New York Times, Feb. 18, 1979]

A COMPANY AT WAR: HOW LILLY DEFENDED DARVON—MARSHALING FORCES IN "RED FLAG ALERT"

(By Peter T. Kilborn)

INDIANAPOLIS.—In 1957, scientists of Eli Lilly & Company here introduced a painkiller that was safer and less addictive than the morphine and codeine that most physicians were then prescribing. The generic name of the drug was propoxyphene hydrochloride, and the brand name, Darvon. In due course, it became the third most prescribed drug in the United States. Then, on Nov. 21, 1978, the media relations director at Lilly, Russell Durbin, received a call from an Associated Press reporter in Washington. What, he asked, had Lilly to say about a petition to ban Darvon?

Thus began a long and wrenching episode for the 103-year-old giant of the pharmaceutical industry. With insulin, the Salk antipolio vaccine in the mid-50's, and an ever-growing stable of antibiotics, Lilly has prided itself on doing