APPENDIX

STATEMENT OF HON. JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION, AND WELFARE

I am announcing today several actions to alert the public to the risks associated with Darvon, and to consider what further steps HEW should take to protect the public.

Darvon—a pain reliever which is also sold under other trade names such as Darvon Compound and Darvocet-N, and under its scientific name, propoxyphene—is the third most frequently described brand name drug in this nation. Last year, 31 million outpatient prescriptions were written for propoxyphene products. Propoxyphene is generally not dangerous when taken as directed; yet it is known to be a dangerous drug in a number of circumstances.

Propoxyphene is now second to barbiturates as the prescription drug most often associated with suicides.

Propoxyphene has also been a cause of accidental deaths, usually when used along with alcohol or tranquilizers.

Propoxyphene is also an addictive drug, though less so than heroin or morphine, and it is often abused.

For all these reasons—suicides, accidental deaths, and potential for addiction—propoxyphene is a drug which has raised serious concerns.

In November 21, 1978, the Health Research Group petitioned me to declare propoxyphene an imminent hazard to health under the Food, Drug, and Cosmetic Act, and to remove the drug immediately from the market. Alternatively, they asked me to recommend to the Attorney General that propoxyphene be shifted from Schedule IV to Schedule II of the Controlled Substances Act, an action which would restrict production and sale of the drug in various ways.

On the basis of the limited evidence now available, I do not believe that there is sufficient justification for the extraordinary step of declaring propoxyphene an imminent hazard and immediately removing it from the market without the opportunity for a hearing.

Accordingly, I am denying the Health Research Group's petition at this time.

However, the current evidence is sufficient to conclude that propoxyphene should be prescribed and taken only with extreme care:

(*a*) Doctors and dentists should not prescribe Darvon or other forms of propoxyphene to people who may be suicidal or addiction prone.

(*b*) Doctors and dentists should warn patients that Darvon and other forms of propoxyphene can be lethal if taken to excess, or if taken along with alcohol of tranquilizers.

(*c*) Pharmacists should be cautious in filling prescriptions for Darvon and other forms of propoxyphene where there is reason to suspect abuse, or where the patient is taking other drugs which may present risks when combined with this drug. Pharmacists should also warn people orally and on prescription labels not to take the drug with alcohol or tranquilizers.

(d) People who do choose to take propoxyphene should be careful not to take it with alcohol or tranquilizers.

These are precautions which health professionals and the public can take on their own to limit the risks from propoxyphene. Although I believe the current evidence does not warrant a finding of imminent hazard at this time, I also believe that this evidence compels us to inform the public promptly of the risks involved. and to evaluate further the dangers of propoxyphene.

Therefore, based on the recommendations of FDA Commissioner Donald Kennedy and of the Surgeon General, Dr. Julius Richmond, I am today directing the Commissioner of the Food and Drug Administration (FDA) and the Surgeon General to take the following actions:

First, within 30 days, to distribute to one million doctors, dentists, pharmacists and other health professionals throughout the country a special Drug Bulletin which will warn of the risks of taking propoxyphene, and urge them to talk with patients about these risks. FDA will also disseminate information on propoxyphene to the public, by means of an article in the FDA Consumer magazine, and through public service announcements in the media.

Second, on April 6, to hold a hearing to allow the public an opportunity to comment on the need for additional FDA regulatory action on propoxyphene, including withdrawing it from the market. The hearing will consider the ways