in which propoxyphene is used, its effectiveness, and its risks. In addition, the FDA will conduct a comprehensive study of the scientific data of propoxyphene, including the evidence and testimony taken recently by Senator Gaylord Nelson's Senate subcommittee.

While I am denying the imminent hazard petition at this time, I have directed Commissioner Kennedy to notify me immediately if, at any time during the course of the public hearings and study of the data, evidence develops which may warrant the declaration of an imminent hazard.

Third, by June 1, to complete the administrative process, including deliberations by an advisory committee, and prepare a recommendation to the Justice Department on whether propoxyphene should be placed under more stringent controls as provided in the Controlled Substances Act. Propoxyphene is currently subject to Schedule IV, which places no limits on production, allows prescriptions to be filled merely by a telephone call by the doctor to the druggist, and permits up to five refills every six months. The Health Research Group has proposed that propoxyphene be transferred to Schedule II, which would place limits on the manufacture of the drug, prohibit dispensing it without a written prescription, and ban refills.

Rather than summarily suspending propoxyphene from the market, I have directed that steps be taken both to protect the public immediately from the health risks, and to conduct a more deliberate, comprehensive review of the facts concerning the drug. In the course of this review, I have asked the FDA actively to solicit the participation in the hearing of doctors, coroners, researchers, and others who have information on propoxyphene.

In the case of propxyphene, these are still unresolved questions which prevent us from saying at this time that it constitutes an imminent hazard to health. But as we take the steps I have announced today, we will develop better answers to these questions, and we will consider whether propoxyphene should be removed from the market as an imminent hazard, whether its removal should be considered in the ordinary administrative process, whether more stringent controls should be placed on its production and sale, and whether the warnings on the labels should be strengthened.

One unresolved question is how extensive is the harm associated with Darvon and other forms of propoxyphene. In 1977, there were 607 propoxyphene-related deaths reported to the Drug Enforcement Administration's Drug Abuse Warning Network (DAWN), which covers about one-third of the United States. This was more deaths than for any other prescription drug, and that fact alone is obviously a cause for concern. However, under the DAWN reporting system, mentions of propoxyphene as related to death can mean merely that the deceased person had the drug in his or her blood, not necessarily that it was in fact the cause of death.

Another unresolved question is the extent to which deaths that are associated with propoxyphene are accidental, result from abuse, or are sucides.

Yet another unresolved question concerning propoxyphene is whether or not it is effective—whether it has any benefits which justify its use despite the risks which exist. Propoxyphene has been a very widely used pain reliever. Propoxyphene is occasionally sold alone, and it may have some therapeutic advantages for people who react adversely to other pain relievers. But it is far more often sold as a compound with pain relievers such as aspirin or acetaminophen. Several studies indicate that most or all of the effectiveness of these combinations is due to the elements other than propoxyphene. Nevertheless, since pain is such a subjective symptom, some people may experience, psychologically or physically, more relief from propoxyphene which is prescribed by a doctor than they would from over-the-counter pain relievers such as aspirin. Overall, the best evidence thus far is that propoxyphene is no more effective—and may be less effective—than aspirin, codeine, and other pain relievers.

Because of these unresolved questions concerning propoxyphene and the uncertainties in the data, I have asked the Commissioner of the FDA to focus on these questions as well as others:

1. What amount of propoxyphene alone is required to produce fatalities? What is the relationship of this amount to the proper dosage? Does propoxyphene build up in the body?

2. Do deaths result when propoxyphene is taken at recommended doses, either alone or in combination with other drugs? How many of the deaths associated with propoxyphene are suicides; how many are accidents resulting from abuse; and how many are accidents resulting from normal use?