hearing is open to all interested persons. Participants are invited to comment on the material presented in this notice and to contribute any additional well-documented information that will be of use to the Commissioner in evaluating efficacy, assessing risks, and analyzing risk/benefit considerations associated with the use of DPX and DPX-containing combinations. Specifically, the objective of the hearing will be to gather evidence on the following issues:

1. Is there "new evidence of clinical experience, not contained in the NDA's or not available to the Food and Drug Administration until after such applications were approved, or are there tests by new methods, or tests by methods not deemed reasonably applicable when the applications were approved which when evaluated together with the evidence available when the applications were approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the applications were approved"? (21 CFR 314.115(b)(2)). Specifically, how many of the deaths associated with DPX are suicides; how many are accidents resulting from abuse or misuse; and how many are accidents resulting from normal use? Are there any deaths resulting from DPX taken at recommended doses, either alone or in combination with alcohol and other drugs? What are the blood levels of DPX and its major metalbolite, norpropoxyphene, that are associated with death, and what is the relationship of these levels to those observed when the drug is taken at recommended doses? What is the mechanism of death in these cases? Is it only respiratory depression, or is there a previously unrecognized effect on cardiac conduction? Are there differences in risk among DPX-containing salts and combinations?

2. Is there "lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof"? (21 CFR 314.115(b)(3)). Specifically, is there scientific evidence that DPX contributes to the analgesic effect of combination products containing aspirin, acetaminophen, or APC, as required by the FDA fixed-combination policy? (21 CFR 300.50(a)). Are there any differences in effectiveness or other benefits among particular salts or combinations of DPX?

In addition, the agency is interested in receiving testimony on whether additional regulatory action is needed at this time with respect to DPX-containing products. Such action could include, but is not necessarily limited to, removal of some or all of these products from the market, rescheduling under the Controlled Substances Act to Schedule III or II, the placing of new warnings in the labeling for physicians or a limitation in the labeling to use in patients who cannot tolerate other analgesics, and/or providing patients with warnings or other information. In a related, though separate, proceeding, the issue of whether DPX should be placed in Schedule II of the Controlled Substances Act, 21 U.S.C. 801 et seq. is being considered by the FDA's Drug Abuse Advisory Committee, which held an initial meeting on the subject on February 13, 1979 and will hold its second and final such meeting on April 17, 1979 to enable FDA to meet a June 1, 1979 deadline set by the Secretary of Health, Education, and Welfare for recommendations on scheduling of DPX. Because that issue is being fully considered in that particular context, it is requested that participants at this hearing not focus primarily on the scheduling issue.

The record of another related proceeding, the testimony at the propoxyphene hearings on January 31, February 1 and 5, 1979 of the Monopoly and Anticompetitive Activities Subcommittee of the Select Committee on Small Business of the U.S. Senate, is already the subject of review and study by FDA. For that reason, it will be unnecessary for participants to duplicate any of that testimony at this hearing.

The hearing will begin at 9 a.m. on April 6, 1979, in the Snow Room (Room 5051), HEW North Building, 330 Independence Ave., SW., Washington, D.C. The presiding officer will be Ronald Kartzinel, M.D., Ph. D., Director of the Division of Neuropharmacological Drug Products, Bureau of Drugs, FDA.

Persons wishing to comment or present views at the hearing must file by March 23, 1979, a written notice of participation under 21 CFR 15.21 with the Hearing Clerk (HFA-305). Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857. The Envelope containing the notice should be prominently marked "Propoxyphene Hearing." The notice of participation should contain the following: Hearing Clerk Docket No. 77N-0266; the name, address and telephone number of the person desiring to make a statement; busi-