suspend approval of the NDA's for propoxyphene-containing products under section 505(e) of the Federal Food, Drug, and Cosmetic Act on the grounds that the continued marketing of these drugs represents an imminent hazard to the public health.

HRG requested alternatively that if the Secretary did not suspend, he support HRG's petition to DEA that propoxyphene be rescheduled as a schedule II narcotic under the Controlled Substances Act.

FDA's Bureau of Drugs is conducting a new review of all data bearing on the safety and effectiveness of propoxyphene including those studies referenced in the HRG petition.

In summary, Mr. Chairman, the current status of propoxyphene presents us with an important and complex regulatory problem. The problems associated with its misuse are indeed troubling; but they must be weighed against significant benefits from the drug.

Propoxyphene is widely used; it provides pain relief for many people. Although it is not a powerful analgesic, it has advantages for persons who cannot tolerate aspirin or acetaminophen. It is prescribed and administered or dispensed in a special medical setting that provides significant psychological amplification of its effects. I am sorry that we cannot offer you a more definitive conclusion at this time. But we are still developing our analysis, Mr. Chairman. These hearings have helped materially in that regard, as well as drawing public attention to a disturbing abuse problem. We will continue to give the matter close scrutiny.

Senator NELSON. When you are saying propoxyphene, are you talking about propoxyphene alone?

Commissioner KENNEDY. Propoxyphene in the totality of its dosage forms and its pattern of distribution.

Senator NELSON. So that I do not forget it, I want to ask again—and you maybe are already reviewing the NRC studies of 1969, covered in your statement here: Is it your policy to continue to evaluate drugs, both prescription and over-the-counter, under the 1962 act? If so, will it be part of this review that you are now making to survey the literature to determine whether or not there is adequate proof of the efficacy—pursuant to the requirements of the statute—of combinations of propoxyphene and acetaminophen, propoxyphene and aspirin? If not, will you pursue the same course the FDA has pursued in the past of requiring companies to come up with controlled studies if, in fact, there is not adequate proof that the drug is effective? Will you require additional evidence to show that, in fact, it meets the statute?

Is that part of the procedure you are now going through?

Commissioner KENNEDY. Yes. We absolutely will review effectiveness information as well as safety information. The procedure for changing the marketing status of the drug is a little different for some of these combination products which are, in fact, post-1962 drugs and are not so-called drugs reviewed under the transitional provisions of the 1962 amendments, but that is a technical difference.

We can and will review the efficacy of the combination products as well as the single dosage.

Senator NELSON. But just a further question. If there are not adequate controlled studies to prove its efficacy in combination, are you or are you not required under the law to request that the studies be made?