to act promptly to suspend approval of an NDA temporarily, and thereby remove the drug from the market, if it represents an "imminent hazard" to the public health. Once having suspended approval, the Secretary must provide the manufacturer with an expedited hearing on whether the drug should be permanently removed from the market. This special authority is vested solely in the Secretary, and may not be delegated.

The summary suspension procedure provides a critical procedural tool to carry out the obligation of this Department and of FDA to protect the public health and safety. Rapid action may be necessary if scientific data raise serious new questions concerning the safety of the drug. If new evidence or further and more careful analysis of existing evidence indicates that a life-threatening or other serious risk is present, the summary suspension procedure allows the Secretary to end promptly this serious risk. The summary procedure does not eliminate the need to conduct a full administrative proceeding to arrive at a final and conclusive judgment as to whether the drug should be permanently removed from the market.

B. Criteria for Suspension

In my 1977 order suspending the NDA's for phenformin under the "imminent hazard" provisions of the Act, I examined at length the text of section 505(e), the legislative history of the suspension provision, and pertinent court decisions. In re New Drug Applications for Phenformin, Order of the Secretary Suspending Approval, pp. 24–35 (DHEW July 15, 1977). I there concluded that the following factors should be weighed in determining whether approval of a new drug application should be suspended on the ground that continued use of the drug will constitute an imminent hazard to the public health:

1. The severity of the harm that could be caused by the drug during the completion of customary administrative proceedings to withdraw the drug from the general market.
2. The likelihood that the drug will cause such harm to users while the administrative process is being completed.
3. The risk to patients currently taking the drug that might be occasioned by the immediate removal of the drug from the market, taking into account the availability of other therapies and the steps necessary for patients to adjust to these other therapies.
4. The likelihood that, after the customary administrative process is completed, the drug will be withdrawn from the general market.
5. The availability of other approaches to protect the public health.

These criteria were reviewed and upheld in *Forsham* v. *Califano*, 442 F. Supp. 203 (D.D.C. 1977).

V. Evaluation of propoxyphene under the criteria for suspension

In analyzing the record in this matter, I have been guided by the expert advice and opinions provided by FDA. In assessing and weighing the evidence, I have recognized that the record of a full evidentiary hearing is not before me.

Under the criteria set forth in part IV above, I am not persuaded that suspension of the propoxyphene NDA's should be ordered at this time. Although I am trouble by the evidence that propoxyphene carries life-threatening risks and is of limited efficacy, I believe that the standards for summary removal of a drug from the market have not been met by the evidence now before me. Therefore, I am denying for the present the HRG petition to declare propoxyphene an imminent hazard.

Nevertheless, because of my concerns about propoxyphene-associated deaths, I have ordered that several steps be taken to minimize as rapidly as possible avoidable harm from the drug and to gather further information on its risks and benefits.

I have directed the Commissioner to have FDA complete expeditiously a comprehensive review of all available information concerning propoxyphene to determine whether the various products containing the drug meet the safety and efficacy requirements of the Act and, thus, whether proceedings should be begun to withdraw the new drug applications for any or all of those products. In the course of this review, FDA will hold a public hearing to receive information and views on the continued marketing of propoxyphene. This hearing is scheduled for April 6, 1979. If at any time during this review evidence appears suggesting that