Data submitted pursuant to the notice have been reviewed and found not to provide substantial evidence that the drugs are effective as fixed combinations for their claimed uses.

In view of the lack of substantial evidence of effectiveness of the drugs as fixed combinations, the recognized potential for abuse of the amphetamine, dextroamphetamine, methamphetamine, and phenmetrazine components, and the availability of alternative therapeutic measures which are safer and effective, the combination products are also regarded as lacking proof of safety. Data submitted in response to the notice of August 8, 1970, do not support a contention that the combination products decrease the incidence or severity of side effects associated with the single ingredient or that the addtional component(s) lessens the abuse potential as compared to that of the single entity anorectic drug. Also, the known adverse effects associated with phenothiazine drugs raises an additional question of safety of use of Eskatrol which contains dextroamphetamine sulfate in combination with prochlorperazine.

With further respect to Eskatrol, the Food and Drug Administration is aware of a study conducted by Dr. Carl Chambers relating to the abuse potential of the product, and for which no report has been submitted by the NDA holder pursuant to section 505(j) of the act and §§ 130.13 and 130.35 of the regulations (21 CFR 130.13 and 130.35).

Therefore, notice is given to the holder(s) of the new drug application(s) and to any other interested person that the Commissioner proposes to issue an order under section 505(e) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the listed new drug application(s) and all amendments and supplements thereto on the grounds that new information before him with respect to the drug(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows that: (1) There is a lack of substantial evidence that the drug(s) will have all the effects they purport or are represented to have; and (2) the drugs are not shown to be safe for use under the conditions of use prescribed, recommended, or suggested in the labeling; and (3) further, in the case of Eskatrol tablets, the applicant has deliberately failed to make required reports in accordance with section 505(j) of the act (21 U.S.C. 355(j)) and § 130.13 and § 130.35 of the new drug regulations (21 CFR 130.13 and 130.35).

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application(s) reviewed. See 21 CFR 130.40 (37 FR 23185, October 31, 1972). Any manufacturer or distributor of such an identical, related, or similar product is an interested person who may in response to this notice submit data and information, request that the new drug application(s) not be withdrawn, request a hearing, and participate as a party in any hearing. Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD–300), 5600 Fishers Lane, Rockville, MD 20852.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner hereby gives the applicant(s) and any other interested person an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn.

The applicant(s) and any other interested person is required to file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–88, 5600 Fishers Lane, Rockville, MD 20852, on or before March 14, 1973, a written appearance electing whether or not to avail himself of the opportunity for a hearing. Failure of an applicant or any other interested person to file a written appearance of election by March 14, 1973, will constitute an election by him not to avail himself of the opportunity for a hearing.

If no person elects to avail himself of the opportunity for a hearing, the Commissioner without further notice will enter a final order withdrawing approval of the application(s).

If an applicant or any other interested person elects to avail himself of the opportunity for a hearing, he must file, on or before March 14, 1973, a written appearance requesting the hearing, giving the reasons why approval of the new drug application(s) should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is