prepared to prove in support of his opposition. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing (21 CFR 130.14(b)).

If review of the data submitted by an applicant or any other interested person warrants the conclusion that there exists substantial evidence demonstrating the effectiveness of the product(s) and evidence that the drug(s) is (are) safe for use for the labeling claims involved (and, in the case of NDA 12-042, that there has been no violation of section 505(j) of the act), the Commissioner will rescind this notice of opportunity for hearing.

If review of the data in the application(s) and data submitted by the applicant(s) or any other interested person in a request for a hearing, together with the reasoning and factual analysis in a request for a hearing, warrants the conclusion that no genuine and substantial issue of fact precludes the withdrawal of approval of the application(s), the Commissioner will enter an order of withdrawal making findings and conclusions on such data.

If, upon the request of the new drug applicant(s) or any other interested person, a hearing is justified, the issues will be defined, a hearing examiner will be named, and he shall Issue, as soon as practicable after March 14, 1973, a written notice of the time and place at which the hearing will commence. All persons interested in identical, related, or similar products covered by the new drug application(s) will be afforded an opportunity to appear at the hearing, file briefs, present evidence, cross-examine witnesses, submit suggested findings of fact, and otherwise participate as a party. The hearing contemplated by this notice will be open to the public except that any portion of the hearing that concerns a method or process the Commissioner finds entitled to protection as a trade secret will not be open to the public, unless the respondent specifies otherwise in his appearance.

Requests for a hearing and/or elections not to request a hearing may be seen in the Office of the Hearing Clerk (address given above) during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 355), and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: February 7, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 73-2716 Filed 2-9-73; 8:45 am]

[DESI 11673]

CERTAIN ORAL ANORECTIC PREPARATIONS: PHENTERMINE HYDROCHLORIDE; PHENDIMETRAZINE TARTRATE; BENZPHETAMINE HYDROCHLORIDE; DIETHYLPROPION HYDROCHLORIDE

DRUGS FOR HUMAN USE; DRUG EFFICACY STUDY IMPLEMENTATION

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following anorectic drugs:

1. Wilpo tablets, containing 8 mg. phentermine hydrochloride per tablet; Dorsey Laboratories, Division of Sandoz-Wander Inc., Northeast, U.S. 6 and Interstate 80, Lincoln, Nebr. 68501 (NDA 12-737).

2. Didrex tablets, containing 25 mg. and 50 mg. benzpetamine hydrochloride per tablet; The Upjohn Co., 7171 Portage Road, Kalamazoo, MI 49001 (NDA 12-427).

3. Plegine tablets, containing 35 mg. phendimetrazine tartrate per tablet; Ayerst Laboratories, Rouses Point, N.Y. 12979 (NDA 12-248).

4. Tepanil tablets, containing 25 mg. diethylpropion hydrochloride per tablet; The Merrell-National Drug Co., Division of Richardson-Merrell, Inc., 110 East Amity Road, Cincinnati, OH 45215 (NDA 11-673).

5. Tenuate tablets, containing 25 mg. diethylpropion hydrochloride per tablet; The Merrell-National Drug Co., Division of Richardson-Merrell, Inc. (NDA 11-722).