6. Preludin Endurets (prolonged-action tablets), containing phenmetrazine hydrochloride; Geigy Pharmaceuticals, Division of Ciba-Geigy Corp., Ardsley, N.Y. 10502 (NDA 11-752).

Although not specifically referred to the Academy for review, Preludin tablets, a conventional oral dosage form containing phenmetrazine hydrochloride (NDA 10-460, Geigy Pharmaceuticals) was approved on the basis of safety prior to 1962, was evaluated by the Academy, and is appropriately included herein.

Such drugs are regarded as new drugs (21 U.S.C. 321 (p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new drug application is required from any person marketing such drug without approval.

I. Sustained-action, time-release, or other delayed or prolonged effect forms of Phenmetrazine Hydrochloride

The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that phenmetrazine hydrochloride in prolonged-action tablet form is less than effective (possibly effective) with respect to any special claim for prolonged action when offered for the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction.

Any data submitted in response to this notice to support claims for which the drug is classified as other than effective must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in § 130.12(a)(5) of the regulations published in the Federal Register of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

II. Conventional tablet forms of Phenmetrazine Hydrochloride; Phentemine Hydrochloride; Benzphetamine Hydrochloride; Phendimetrazine Tartrate; or Dichylpropion Hydrochloride

A. *Effectiveness classification.*—The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that these drugs, administered in conventional oral dosage form, are effective in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction.

B. *Conditions for approval and marketing.*—The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* Such preparations are in tablet dosage form suitable for oral administration.

2. *Labeling conditions.* The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

The drugs are labeled to comply with all requirements of the Act and regulations, and the labeling bears adequate information for safe and effective use of the drug(s). The "Indications" section is as follows:

INDICATIONS

(*Name of drug*) is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class (see Actions) should be measured against possible risk factors inherent in their use such as those described below.

In addition, the labeling contains the following "Actions" section and drug dependence warning the "Warnings" section:

ACTIONS

(*Name of drug*) is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, the amphetamines. Actions include central nervous system stimulation and elevation and blood pressure. Tachyphylaxis and tolerance have been demonstrated with all drugs of this class in which these phenomena have been looked for.