

Other drugs (combination anorectic drugs) were also included in the notice of August 8, 1970. They are not affected by this notice.

In addition to the holder(s) of the new drug application(s) specifically named above, this notice applies to all persons who manufacture or distribute a drug product, not the subject of an approved new drug application, which is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (HFD-300), 5600 Fishers Lane, Rockville, MD 20852.

The August 8, 1970 notice stated that the above-listed drugs were regarded as lacking substantial evidence of effectiveness for specific indications; and possibly effective for their claimed anorectic effects, for their claims for prolonged, continuous or sustained release, and for certain other claims.

Based on information submitted by the manufacturers of anorectic drugs and a review of available evidence, the Commissioner of Food and Drugs finds it appropriate to amend the announcement of August 8, 1970 insofar as it pertains to the drugs listed above, as set forth below.

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.

A. Effectiveness classification.—The Food and Drug Administration has considered the Academy's reports as well as other available evidence and concludes that:

1. All of the drugs listed above are effective in the management of exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction.

2. Dextroamphetamine and amphetamine are also effective for narcolepsy and for minimal brain dysfunction in children (hyperkinetic behavior disorders), as an aid to general management.

3. All of the drugs lack substantial evidence of effectiveness for all other of their claims.

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.* The preparations are in capsule, tablet, or liquid form as indicated above, suitable for oral administration.

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

- b. The drug is 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. The Indications, Actions, and the Drug Dependence portions of the Warnings sections are as follows (Complete labeling guidelines are available on request):

FOR PHENTERMINE AND DIETHYLPROPION HYDROCHLORIDE

Indication

(Name of drug) is indicated in the management of exogenous obesity as a short-term (a few weeks) adjunct 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.

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 of blood pressure. Tachyphylaxis and tolerance have been demonstrated with all drugs of this class in which these phenomena have been looked for.

Drugs of this class used in obesity are commonly known as "anorectics" or "anorexigenics". It has not been established, however, that the action of such