have not been cleared through the effectiveness provisions of the Drug Amendments of 1962 (Public Law 87-781 which amended the Federal Food, Drug, and Cosmetic Act). These drugs are very extensively used in the treatment of obesity. The extent of use for such purposes as narcolepsy and minimal brain dysfunction in children is believed to be minor as compared with the total usage of these drugs. Because of their stimulant effect on the central nervous system, they have a potential for misuse by those to whom they are available through a physician's prescription, and their abuse by those who obtain them through illicit channels is well documented. Production data indicate that amphetamines have been produced and prescribed in quantities greatly in excess of demonstrated medical needs.

(3) Pursuant to a notice published in the FEDERAL REGISTER of August 8, 1970 (35 FR 12652), which required the submission of new drug applications as a condition for continued marketing of amphetamines, 106 new drug applications for amphetamines or amphetamine-containing drug products were received. The data submitted in those applications, and data obtained from other sources concerning anorectic drugs, generally supported the efficacy of anorectic drugs.

(b) On the basis of currently available evidence derived from short-term studies, the Commissioner concludes that single drug entity oral dosage forms of amphetamine or dextroamphetamine 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 restrictions, for patients in whom obesity is refractory to other measures. For purposes of this regulation, a mixture of dextroamphetamine and amphetamine is ordinarily regarded as a single drug entity.

(c) The Food and Drug Administration is not aware of data providing substantial evidence of the effectiveness of levamfetamine and its salts and regards these preparations as new drugs requiring approval full new-drug applications.

(d) In view of the well-documented history of abuse of parenteral amphetamines the severe risk of drug dependence, and the availability of safer alternative parenteral drugs which are equally effective for recognized non-anorectic indications, the Food and Drug Administration regards parenteral amphetamines as lacking evidence of safety.

(e) Any combination drug containing amphetamine or dextroamphetamine is regarded as a new drug requiring an approved full new-drug application as a condition for marketing. Data in new-drug applications are required to fulfill the criteria set forth in § 3.86 governing fixed combination prescription drugs for humans.

(f) New drug applications have been received from persons marketing orally administered single entity amphetamine or dextroamphetamine dosage forms. Any other person who intends to market such drug is required to submit to the Food and Drug Administration an abbreviated new drug application (§ 130.4 (f)) except that in addition, the application shall contain full information required under items 7 and 8 (composition and methods, facilities, and controls) of the new drug application form FD-356H (§130.4(c)).

(g) The labeling conditions for single entity oral dosage forms of amphetamine and dextroamphetamine and their salts are as follows:

(1) The label shall bear the statement "Caution: Federal law prohibits dispensing without prescription".

(2) The drug shall be labeled to comply with all requirements of the act and regulations. The labeling shall bear adequate information for safe and effective use of the drug. The indications for use are:

Narcolepsy.

Minimal brain dysfunction in children (hyperkinetic behavior disorders), as an aid to general management.

Management of exogenous obesity as short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to other measures.

(3) Complete labeling guidelines are available from the Food and Drug Administration.

(h) Regulatory proceedings will be initiated with regard to any such drug within the jurisdiction of the act which is not in accord with this regulaton.

Effective date. This regulation shall be effective on March 14, 1973.

Dated: February 7, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.