

This notice is issued pursuant to provisions of the Federal Food, Drug and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: July 30, 1970.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

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RULES AND REGULATIONS

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER C—DRUGS

PART 130—NEW DRUGS

Subpart A—Procedural and Interpretative Regulations

AMPHETAMINES (AMPHETAMINE, DEXTROAMPHETAMINE, AND THEIR SALTS, AND LEVAMFETAMINE AND ITS SALTS) FOR HUMAN USE; STATEMENT OF POLICY

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502(f), (j), 505, 701(a), 52 Stat. 1051-53, as amended, 1055; 21 U.S.C. 352(f), (j), 355, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), Part 130 is amended by adding to Subpart A the following new section:

§ 130.46 Amphetamines (amphetamine, dextroamphetamine, and their salts and levamfetamine and its salts) for human use; statement of policy.

(a) *Amphetamine and dextroamphetamine and their salts.* (1) Pursuant to the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, has evaluated certain dosage forms of amphetamines and other sympathomimetic stimulant drugs intended for use in the treatment of obesity and for other uses. The Academy found that such drugs as a class have been shown to have a generally short-term anorectic action. They further commented that clinical opinion on the contribution of the sympathomimetic stimulants in a weight reduction program varies widely, the anorectic effect of these drugs often plateaus or diminishes after a few weeks, most studies of them are for short periods, no available evidence shows that use of anorectics alters the natural history of obesity, some evidence indicates that anorectic effects may be strongly influenced by the suggestibility of the patient, and reservations exist about the adequacy of the controls in some of the clinical studies. Their significant potential for drug abuse was also cited.

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PRECAUTIONS

Caution is to be exercised in prescribing amphetamines for patients with even mild hypertension.

Insulin requirements in diabetes mellitus may be altered in association with the use of amphetamines and the concomitant dietary regimen.

Amphetamines may decrease the hypotensive effect of guanethidine.

The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage.