

15116 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(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 regulation.

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

Dated: February 7, 1973.

WILLIAM F. RANDOLPH,

Acting Associate Commissioner for Compliance.

[FR Doc. 73-2717 Filed 2-9-73; 8:45 am]

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NOTICES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

[DESI 5378; Docket No. FDC-D-582; NDA No. 9-946 etc.]

CERTAIN COMBINATION ANORECTIC DRUGS

OPPORTUNITY FOR HEARING ON PROPOSAL TO WITHDRAW APPROVAL OF NEW DRUG APPLICATIONS

In a notice (DESI 5378) published in the FEDERAL REGISTER of August 8, 1970 (35 FR 12678), the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the drugs described below stating that the drugs were regarded as possibly effective and lacking substantial evidence of effectiveness for the various labeled indications.

NDA No.	Drug	NDA Holder
9-946.....	Du-Oria tablets containing 10 mg methamphetamine hydrochloride, and 0.25 mg reserpine per sustained release tablet.	Formerly marketed by B. F. Ascher & Co., Inc., Post Office Box 827, Kansas City, Mo. 64130.
10-207.....	Dexserpine "5" tablets containing 5 mg dextroamphetamine sulfate and 0.1 mg reserpine per tablet.	Formerly marketed by Nysco Laboratories, Inc., 34-24 Vernon Blvd., Long Island City, N.Y. 11106.
11-280.....	Bamadex tablets containing 5 mg dextroamphetamine sulfate and 400 mg meprobamate per tablet.	Lederle Laboratories Division, American Cyanamid Co., Post Office Box 500, Pearl River, N.Y. 10965.
11-522.....	Obetrol-10 and Obetrol-20 tablets, respectively, containing 2.5 mg each or 5 mg each of methamphetamine saccharate, methamphetamine hydrochloride, amphetamine sulfate, dextroamphetamine sulfate per tablet.	Obetrol Pharmaceuticals, Division of Rexar Pharmacal Corp., 382 Schenck Ave., Brooklyn, N.Y. 11207.
11-538.....	Biphetamine-T "12 1/2" capsules and Biphetamine-T "20" capsules, respectively, containing 6.25 mg each of dextroamphetamine and amphetamine, and 40 mg methaqualone per capsule, and 10 mg each of dextroamphetamine and amphetamine and 40 mg methaqualone per capsule, all as cation exchange resin complexes of sulfonated polystyrene.	Strassenburgh Pharmaceutical, Division Pennwalt Corp., 755 Jefferson Rd., Rochester N.Y. 11623.
12-042.....	Eskatrol Spansules containing 15 mg dextroamphetamine sulfate and 7.5 mg prochlorperazine (as the malate) per sustained release capsule.	Smith Kline & French Laboratories, 1500 Spring Garden St., Philadelphia, Pa. 19101.
12-127.....	Appetrol tablets containing 5 mg dextroamphetamine sulfate and 400 mg meprobamate per tablet.	Wallace Pharmaceuticals, Division of Carter-Wallace, Inc., Half Acre Rd., Cranbury, N.J. 08512.
12-371.....	Prelu-Vite capsules containing 25 mg phenmetrazine hydrochloride, 2,000 USP units vitamin A, 200 USP units vitamin D, 2 mg thiamine mononitrate, 2 mg riboflavin, 20 mg niacinamide, 3 mg calcium pantothenate, 1 mg pyridoxine hydrochloride, 0.5 mg cobalamin concentrate, 37.5 mg ascorbic acid, 5 mg iron, 140 mg calcium, 108 mg phosphorus, 0.1 mg iodine and 1 mg copper per capsule.	Formerly marketed by Geigy Pharmaceuticals, Division of Ciba Geigy Co., Saw Mill River Rd., Ardsley, N.Y. 10502.
12-415.....	Delfeata-sed Stedytabs containing 30 mg di-methamphetamine hydrochloride and 120 mg amobarbital per sustained-release tablet.	Eastern Research Laboratories Inc., 302 South Central Ave., Baltimore, Md. 21202.
12-570.....	Bamadex Sequels containing 15 mg dextroamphetamine sulfate and 300 mg meprobamate per sustained-release capsule.	Lederle Laboratories Division, American Cyanamid.
12-624.....	Appetrol-S.R. capsules containing 15 mg dextroamphetamine sulfate and 300 mg meprobamate per sustained-released capsule.	Wallace Pharmaceuticals.