6382. Trim-A-Drine timed disintegration capsules. (F.D.C. No. 43911. S. No. 77-702 P.)

QUANTITY: 100 capsules in bulk btls. and 34 retail btls. at Detroit, Mich., in possession of Marshall Drug Co.

SHIPPED: 8-10-59, from Philadelphia, Pa.

LABEL IN PART: (Bulk btl.) "Timcaps Phenylpropanolamine HCl. * * * 75 mg. * * * Each Timcap Contains: Phenylpropanolamine HCl_____75 mg. Medication released gradually over a period of approximately 8 to 10 hours. Effective orally for the symptomatic control of allergic manifestations, appetite depressant, and vasoconstrictor. Caution: * * * Dosage: * * * 10397 Lustgarten Laboratories, Inc., Philadelphia 31" and (retail btl.) "21 Timed-Caps * * * Trim-A-Drine True Appetite Depressant * * * Each Timed-Cap contains 75 mg. phenylpropanolamine HCl which is released over a period of 6-10 hrs. * * * Distributed by Marshall Drug Co., 14230 Curtis Ave., Detroit 35, Mich. 1039."

ACCOMPANYING LABELING: Flyers reading in part "True Appetite Depressant * * * Marshall Drug Co." and loose retail bottle labels.

LIBELED: 11-16-59, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that it was an appetite depressant and that it would cause one to become slim and lean; and 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 11-10-60. Consent—destruction.

6383. Delfeta-Sed Stedytabs and Delfeta-Sed plus T Stedytabs. (F.D.C. No. 44676. S. Nos. 3-801/2 R.)

QUANTITY: 2 drums, containing 42,000 tablets (Lot No. 996) and 61,000 tablets (Lot No. 997) respectively in bulk, 10,000 tablets in unlabeled cellophane bags, and 250 30-tablet pkgs. at Baltimore, Md.

SHIPPED: On 4-25-60 and 4-26-60, from St. Louis, Mo., by Victor M. Hermelin & Co.

LABEL IN PART: (Drum) "Lot No. 996 * * * Delfeta-Sed Stedytabs Each tablet contains: *Delfetamine 30 mg. #Sedafax 120 mg. (Warning: May be habit forming) * * * *Registered Trademark of dl-N-methyl-beta-phenylisopropylamine Hydrochloride. #Trademark of special micronized grade of Amobarbital, USP;" (drum) "Lot No. 997 * * * Delfeta-Sed plus T Stedytabs Each tablet contains: *Delfetamine 30 mg. #Sedafax 120 mg. (Warning: May be habit forming) §Triroid 2¼ gr. * * * *Registered Trademark of dl-N-methyl-beta-phenylisopropylamine Hydrochloride. #Trademark of special micronized grade of Amobarbital, USP §Trademark of triple-assayed Thyroid, USP;" and (30-tablet pkgs.) "Stedytabs Sustained Release Tablets Delfeta-Sed plus T Delfetamine with Sedafax & Triroid."

RESULTS OF INVESTIGATION: Investigation revealed that the 10,000 tablets in unlabeled cellophane bags were rejects of Lot No. 997; and that the 250 30-tablet packages contained tablets repacked by Eastern Research Laboratories, Inc., from Lot No. 997. The tablets of Lot No. 996 contained methamphetamine hydrochloride and amobarbital and those of Lot No. 997 contained methamphetamine hydrochloride, thyroid, and amobarbital.

LIBELED: 6-21-60, Dist. Md.

CHARGE: 502(d)—the articles contained a chemical derivative of barbituric acid, and their labels failed to bear the name of the drug and, in juxtaposition therewith, the statement "Warning: May be habit forming."; and 505(a)—the articles were new drugs which may not be introduced into interstate commerce, since applications filed pursuant to law were not effective with respect to such drugs.

DISPOSITION: 8-8-60. Default—destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

6384. Amphetamine sulfate (tablets and capsules). (F.D.C. No. 43626. S. No. 75-606 P.)

QUANTITY: Unknown quantity of tablets and capsules at Cairo, Ill.

SHIPPED: Prior to 10-26-59, from places outside the State of Illinois.

LIBELED: 10-28-59, E. Dist. Ill.

CHARGE: 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was not exempt from such labeling since the article was, or would, be in possession of persons not regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs and since the article was not to be dispensed as required by 503(b); 503(b)(1)—the article was a drug intended for use by man which, because of its toxicity or other potentiality for harmful effect and the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug and it was dispensed contrary to the provisions of such Section; and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12-15-59. Default—delivered to the Food and Drug Administration.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

6385. Dextro-amphetamine sulfate tablets and capsules and amphetamine sulfate tablets and capsules. (F.D.C. No. 43553. S. No. 75-813 P.)

QUANTITY: Unknown quantity of tablets and capsules at Wyatt, Mo.

SHIPPED: On an unknown date from Cairo, Ill., by Thurman L. Wilkerson, also known as Bo Wilkerson.

LIBELED: 10-28-59, E. Dist. Mo.

CHARGE: 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was not exempt from such labeling since the article was, or would be, in pos-

*See also No. 6384.