

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6704. Vitamin tablets and vitamin-and-mineral tablets. (F.D.C. Nos. 46275, 46278. S. Nos. 78-747/8 R.)

QUANTITY: 94 btl., each containing 50 or 100 *vitamin-and-mineral tablets*, at Mission, Tex.; and 42 btl., each containing 50 or 100 *vitamin tablets*, at Donna, Tex.

SHIPPED: On unknown dates, from Chicago, Ill.

LABEL IN PART: (Btl.) "Olavite-M Therapeutic Vitamin & Mineral Tablets * * * Olafsen Vitamins, Inc., Dist. Chicago, Illinois. Each tablet contains * * * Folic Acid 0.5 mg. * * * Dosage: 1 or 2 tablets daily," and "Olavite Therapeutic Vitamin Tablets * * * Olafsen Vitamins, Inc., Dist., Chicago, Illinois. Each tablet contains * * * Folic Acid 0.5 mg. * * * Dosage: 1 or 2 tablets daily."

LIBELED: 8-24-61, S. Dist. Tex.

CHARGE: 503(b)(4)—while held for sale, the labels of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-9-61. Default—destruction.

6705. Viril-Lam tablets. (F.D.C. No. 45947. S. No. 32-285 R.)

QUANTITY: 389 25-tablet btl. at Santurce, P.R.

SHIPPED: 3-31-61, from Oceanside, N.Y., by Lambda Pharmacal Laboratories.

LABEL IN PART: "Lambda Viril-Lam Each tablet supplies: Methyl testosterone 10 mg. Pituitary extract (anterior lobe) 4 mg. Adrenals 4 mg. Yohimbine hydrochloride 5 mg. Vit. A (from Fish liver oil) 5,000 U.S.P. Units Vitamin E 1 mg. Vitamin B₁ 5 mg. Zinc Phosphide 1.5 mg. Strychnine sulfate 0.05 mg. Dosage: * * * Lambda Pharmacal Laboratories, Inc., 391 Atlantic Ave., Oceanside, N.Y."

LIBELED: 6-20-61, Dist. P.R.

CHARGE: 503(b)(4)—when shipped, the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8-10-61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

6706. Candy-coated chewing gum. (F.D.C. No. 46440. S. No. 84-605 R.)

QUANTITY: 7 ctns., containing a total of 6,000 units, at New York, N.Y., in possession of Kean Energizing Health Products, Inc.

SHIPPED: 5-1-61, from Newark, N.J.

LABEL IN PART: (Plastic box) "15 One For The Road 15 Natural Coffee Base 'Drive-Safers' Pep-Ups Kean Brand Chicles Vitamin A Fortified Caffeine Activated Safe-Pleasant as Coffee * * * An Adult Product," "2 Pep-Ups* Chicles Provide the Energy & Stimulation of One Full Cup of Coffee, Chew As Many As Desired," and "Each Chicle Contains 5000 Units Vitamin A To Aid Eyesight Fatigue Resist Headlight Glare."

ACCOMPANYING LABELING: A package insert reading in part "Real Coffee Base plus Vitamin A and Caffeine"; a folder reading in part "New! Chew A Full Cup of Zesty Coffee Kean's Pep-Ups Brand"; a window streamer reading in

part "Here NOW! Real Coffee Base Caffeine Activated Vitamin 'A' Fortified Kean's Pep-Ups Brand Chicles, Only Chewing Gum of its Kind in the World"; form letter headed "Kean Energizing Health Products"; and display box inserts reading in part "New! * * * Pep-Ups* Awakeners— 'Drive Safers' Alerters."

RESULTS OF INVESTIGATION: The article was in bulk form and was, in the normal course of the dealer's business operations, to be repacked into clear plastic 15-unit rectangular boxes containing insert labels.

The label on the bulk material stated that the article contained "½ gr. anhydrous Caffeine per tablet" which was about ⅓ of the caffeine content of a cup of coffee.

LIBELED: 9-18-61, S. Dist, N.Y.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was capable of making one energetic; awakening, and promoting alertness and safer driving; aiding or resisting "eyesight fatigue" resulting from exposure to sun, daylight, headlight glare, and artificial lighting; having a sobering and counteractive effect in mild hangover condition; overcoming car sickness; and that the article was the only chewing gum of its kind in the world; that it contained a significant amount of caffeine which was "activated," "activating," and "fortified"; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which it was offered.

DISPOSITION: 11-8-61. Consent—claimed by the dealer and destroyed.

6707. Various prescription drugs. (F.D.C. No. 46438. S. Nos. 3-181/8 T.)

QUANTITY: Various quantities, having an approximate total value of \$1,000, at Baltimore, Md., in possession of Golditch Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample Not To Be Sold," "Physician Sample," "Complimentary Package," "Sample Not For Sale," and "Physician Sample Not To Be Sold," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked by the dealer from physicians' samples into bottles to which had been affixed labels bearing the brand names of the drugs, the words "Professional Sample Not To Be Sold," "Complimentary Package," "Sample Not For Sale," or similar wording, and the names and addresses of the manufacturers, packers, or distributors located outside the State of Maryland.

Some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, which had not, at the time the articles were libeled, been repacked by the dealer and which bore labels similar to the above articles.

Some of the articles were prescription drugs repacked as above from physicians' samples into bottles bearing labels which contained the words "Physician Sample" or similar wording and such brand names for the drugs as are indicative of their manufacture outside the State of Maryland, but did not bear the names and addresses of the manufacturers, packers, or distributors located outside the State of Maryland.

Some of the articles were prescription drugs which had been repacked by the dealer into bottles to which had been affixed labels bearing such brand names for the drugs as were indicative of their manufacture outside the State of Maryland, but which did not contain the names and addresses of the manu-