

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