

SHIPPED: On 6-4-58, tablets were shipped in bulk drum, from Cleveland, Ohio.

LABEL IN PART: (Btl.) "Estrophen-B Regular Strength, Hexestrol, Phenobarbital and Vitamin B Complex Factors Each tablet contains: * * * Thiamine Hydrochloride 3 mg." and (drum) "Estrophen-B Regular Strength * * * Thiamine Hydrochloride 3 mg."

RESULTS OF INVESTIGATION: The tablets shipped in bulk were repacked in bottles by the dealer. Examination showed that the article contained approximately 70 percent of the declared amount of thiamine hydrochloride (vitamin B₁).

LIBELED: 7-19-60, E. Dist. Va.; amended 7-25-60.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported or was represented to possess; and 502(a)—while held for sale, the labeling of the article was false and misleading as applied to a product which contained less than the declared amount of thiamine hydrochloride.

DISPOSITION: 9-27-60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

6391. Lecithin. (F.D.C. No. 44438. S. Nos. 93-216 P, 93-218/20 P.)

QUANTITY: 37 8-oz. btls. and 28 1-lb. btls. of granular lecithin; 16 100-capsule btls. of No. 761 lecithin; 5 50-capsule btls., 13 100-capsule btls., and 4 250-capsule btls. of liquid lecithin; and 13 100-capsule btls. of soyalecithin and carotene, at Seattle, Wash.

SHIPPED: (Granular lecithin) 1-15-60, from Los Angeles, Calif., by William T. Thompson Co.; (No. 761 lecithin) 1-27-60, from New York, N.Y., by Approved Formulas, Inc.; (liquid lecithin) between 10-2-59 and 11-13-59, from Portland, Oreg., by Nu Vita Co.; and (soyalecithin and carotene) 10-20-59, from South Hackensack, N.J., by Schiff Bio Food Products, Inc.

LABEL IN PART: "Granular Form Wm. Luddy Co. Lecithin Derived From Soybeans * * * A Natural Vegetable phosphatide rich in unsaturated fatty acids * * * Wm. Luddy Company, Los Angeles 27, Calif. St. Louis 3, Mo."; "No. 761 Lecithin 8 Grains natural lecithin obtained from soybeans aids fat metabolism. * * * Manufactured for Approved Formulas, Inc., New York 36, N.Y."; "Soya Liquid Lecithin US Grade * * * Each capsule contains not less than 1200 mg. of N.S. grade Lecithin * * * Nu Vita Company, 1325 S.E. 9th Avenue Portland 14, Oregon"; and "Schiff Natural Lecithin Soyalecithin 370.6 mg. & Carotene Vitamin A 1000 units per capsule * * * Schiff Bio Food Products, Inc., So. Hackensack, N.J."

ACCOMPANYING LABELING: Photocopy of a newspaper article by Lelord Kordell entitled "Stay Alive Longer" appearing in the August 26, 1959 edition of a Seattle newspaper.

LIBELED: 4-19-60, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of, atherosclerosis; pale and drawn face;

*See also Nos. 6382, 6389, 6390.

nervousness; weak, jangly nervous system; insomnia; irritability; nervous, mental, and glandular overactivity; exhaustion; loss of vitality of the cerebrospinal fluid; nerve and gland exhaustion; nervous breakdown; headaches; brain fog; senility; nervousness; tension; shattered nerves; depleted brain power; waning activity of vital glands; depletion of fatty myelin sheath of nerves; sexual decline; and fat infiltration of the liver and other organs; and that the articles would effect a strong nervous system; improve the functioning of the brain, nervous system, endocrine glands, muscles of the heart and kidneys; neutralize body poisons of internal and external origin; prevent fat settling on artery walls; and restore life forces; and that the granular lecithin was adequate and effective to lower the cholesterol level of the blood.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 26797.

DISPOSITION: 6-17-60. Default—destruction.

6392. Gelatin Plus capsules. (F.D.C. No. 44688. S. Nos. 25-917/8 R.)

QUANTITY: 106 ctns., each containing 12 boxes of 90 capsules each; 96 ctns., each containing 12 boxes of 30 capsules each; 285 ctns., each containing 8 boxes of 30 capsules each; 156 ctns., each containing 1 box of 30 capsules each; 2 boxes of 5 capsules each; and 1 box of 15 capsules, at Santa Monica, Calif., in possession of Gelatin Plus, Inc.

SHIPPED: On 4-8-60 and 5-17-60, quantities of bulk gelatin were shipped from Detroit, Mich.

LABEL IN PART: (Box) "Gelatin-Plus for Problem Nails * * * Ten-Gr. Capsules * * * A pure High Protein Sugarless Gelatin containing natural Amino Acids with added Assimilable Calcium in the ratio of the proportion of the Adult Daily Requirement .009% Directions * * * Distributed by Gelatin Plus * * * Santa Monica, Calif."

RESULTS OF INVESTIGATION: The bulk gelatin, after its shipment as described above, was encapsulated and packaged by Gelatin Plus, Inc.

LIBELED: 6-27-60, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was effective for the treatment of problem nails that split, chip, peel, and break, and that it would produce "nail beauty."

DISPOSITION: 10-30-60. Default—destruction.

✓ 6393. Concentrated extract of alfalfa. (F.D.C. No. 44666. S. No. 41-445 R.)

QUANTITY: 8 cases, 24 8-oz. btls. each; 6 cases, 13 16-oz. btls. each; and 9 cases, 12 32-oz. btls. each, at San Francisco, Calif.

SHIPPED: 6-8-59 and 1-8-60, from American Fork, Utah, by Lucerne Laboratories of Utah.

LABEL IN PART: (Btl.) "Lucerne Concentrated extract of alfalfa (Medicago Sativa) it is a dietary supplement * * * Lucerne Is Not A Medicine One teaspoonful (5 Mls) contains: * * * 0.00586 Mg. Iron Three glasses daily furnish: * * * 0.02 mg. 12% of Min. Daily Req. * * * Also micro-amounts of the many other elements present, (and combined naturally) in the Lucerne,—the oldest known plant—from which made; for which elements no official standard of requirement has been established. Many of these elements may be deficient in foods of every day variety. * * * All materials used in the