

ditions, hay fever and head colds; and for providing benefits to the bladder, kidneys, and related parts.

DISPOSITION: 12-18-59. The defendant having consented, the court entered a decree of permanent injunction enjoining and restraining the defendant from making or causing to be made any oral or written representations for the use of the article in the prevention or cure of any disease, condition, or infection of any kind which was not stated in the labeling of the article, while such article was held for sale after shipment in interstate commerce.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

6388. Sulfapyridine sodium powder (2 seizure actions). (F.D.C. Nos. 44699, 44700. S. Nos. 41-268/70 R.)

QUANTITY: 1 100-lb. drum, 8 1-lb. btl., and 1 25-lb. drum, at San Francisco, Calif.

SHIPPED: The article was shipped in bulk, on 10-8-58, from New York, N.Y., by Fine Chemical Co.

LABEL IN PART: (Drum) "Sodium Sulfapyridine N.F.X. For Manufacturing Use Only Fine Chemical Company, New York, N.Y."; (btl.) "Sulfapyridine Sodium N.F. Powder (Not Sterile) Trico Pharmaceutical Co. Oregon City-San Francisco-Los Angeles"; and (drum) "Sulfapyridine Sodium N.F. Powder Not Sterile (Trico Pharmaceutical Co.)"

RESULTS OF INVESTIGATION: A portion of the bulk drug was repacked into 8 1-lb. bottles and 1 25-lb. drum after shipment. Analysis showed that the drug contained less than 99 percent sulfapyridine sodium.

LIBELED: 7-5-60, N. Dist. Calif.

CHARGE: 501(b)—when shipped, the strength of the article differed from the standard set forth in the National Formulary.

DISPOSITION: 8-24-60. Default—destruction.

6389. Tweltone solution. (F.D.C. No. 44756. S. No. 22-273 R.)

QUANTITY: 48 cartoned vials at Kansas City, Mo.

SHIPPED: 4-4-60, from Indianapolis, Ind., by Pitman-Moore Co.

LABEL IN PART: "10 cc. size Sterile Solution Tweltone Liver Folic Acid B₁₂ * * * Pitman-Moore Company Div. of Allied Labs., Inc., Indianapolis. Sterility Test: 19464 Serial Lot No. 22159070."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 50 percent of the declared amount of vitamin B₁₂.

LIBELED: On or about 7-26-60, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Each cc. Represents: Vitamin B₁₂ Activity * * * Equivalent to 10 Micrograms Cyanocobalamin, Fortified With Folic Acid, 10 mg. and Crystalline Vitamin B₁₂ 50 Micrograms." was false and misleading.

DISPOSITION: 9-23-60. Default—destruction.

6390. Estrophen-B Regular Strength tablets. (F.D.C. No. 44732. S. No. 4-504 R.)

QUANTITY: 1 drum containing 18,000 tablets in bulk, 96 100-tablet btl., and 1 1,000-tablet btl., at Petersburg, Va.

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.