

LIBELED: 2-10-62, N. Dist. Iowa.

CHARGE: 402(a)(2)(C)—when shipped, the article contained a food additive, namely, folic acid, which is unsafe within the meaning of 409, since it and its use or intended use were not in conformity with a regulation or exemption in effect pursuant to 409.

DISPOSITION: 3-15-62. Default—destruction.

28192. Pen-Tone Vitamin Tonic. (F.D.C. No. 47417. S. No. 43-689 T.)

QUANTITY: 44 cases, each containing 12 btls., at Philadelphia, Pa.

SHIPPED: In 1959, from New York, N.Y., by Biopharma, Inc.

LABEL IN PART: (Btl.) "Twelve Fluid Ounces Pen-Tone High Potency Vitamin Tonic Contains Vitamins B-12, B-1, B-2, Nicotinamide, B-6, Panthenol and Folic Acid Plus Iron * * * Distributed by Penhurst Pharmacal Co. Distributors, Phila. Pa. Each Fluid Ounce (2 tablespoonfuls) contains: * * * Folic Acid 1 mg. Dosage: * * * Adults: Two Tablespoonfuls daily."

LIBELED: 3-27-62, E. Dist. Pa.

CHARGE: 402(a)(2)(C)—while held for sale, the article contained folic acid, a food additive, which is unsafe within the meaning of 409, since it and its use or intended use was not in conformity with a regulation or exemption in effect pursuant to 409; and 403(j)—when shipped, the article purported to be and was represented as a food for special dietary use by reason of its vitamin content, and its label failed to bear, as required by regulations, a statement of the proportion of the minimum daily requirement for niacinamide (nicotinamide) supplied by such food when consumed in a specified quantity during a period of one day.

DISPOSITION: 5-2-62. Default—destruction.

28193. Candee-Vite tablets. (F.D.C. No. 47452. S. No. 4-739 T.)

QUANTITY: 476 50-tablet btls. at Norfolk, Va.

SHIPPED: 4-30-58, from Long Island City, N.Y.

LABEL IN PART: (Btl.) "Candee-Vite * * * Each Tablet Contains: Vitamin A Acetate—2500 Units * * * Ascorbic Acid—30 mgm. * * * Control Number 34096 Rx Products Co., Inc., Norfolk, Virginia Distributors."

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 28 percent of the declared amount of vitamin A acetate and approximately 66 percent of the declared amount of ascorbic acid.

LIBELED: 4-13-62, E. Dist. Va.

CHARGE: 402(b)(1)—while held for sale, the valuable constituents, namely, vitamin A acetate and ascorbic acid, had been wholly or in part omitted or abstracted from the article; and 403(a)—the label statement "Each Tablet Contains: Vitamin A acetate 2500 Units * * * Ascorbic Acid 30 mgm." was false and misleading.

DISPOSITION: 5-14-62. Default—destruction.

28194. Calvitran capsules. (F.D.C. No. 47031. S. No. 17-352 T.)

QUANTITY: 6 cases, 48 btls. each, at Chattanooga, Tenn.

SHIPPED: 5-13-59, from Long Island City, N.Y.

LABEL IN PART: (Btl.) "Calvitran Phosphorous Free A Vitamin and Mineral Supplement For Use in Prenatal care and Lactation. Each Captab Contains * * * Folic Acid 1 mg."

LIBELED: 2-12-62, E. Dist. Tenn.

CHARGE: 402(a)(2)(C)—while held for sale, the article contained a food additive, namely, folic acid, which is unsafe within the meaning of 409, since it and its use or intended use were not in conformity with a regulation or exemption in effect pursuant to 409.

DISPOSITION: 4-19-62. Default—destruction.

28195, Liver, iron, and folic acid capsules. (F.D.C. No. 45728. S. No. 64-433 R.)

QUANTITY: 117 100-capsule btl. at San Francisco, Calif.

SHIPPED: Between April 1960 and July 1960, from St. Louis, Mo., by Rexall Drug & Chemical Co.

LABEL IN PART: "Sears Approved * * * Improved Liver, Iron, Folic Acid, Vitamins B₁₂ and C Formula with Vitamins A, D and E added a dietary supplement fortified with elements to aid red blood cell formation, plus valuable Vitamin C. Each capsule supplies 250 mg. of liver, rich source of B-complex factors, plus valuable Vitamin B₁₂. Contents: * * * Each Capsule Contains: * * * Folic Acid U.S.P. 2 mg. * * * Vitamin E * * * 2 I.U.** * * * The liver in this product is a source of other members of the B-Complex. * * * ** The need for this substance in human nutrition has not been established. * * * Distributed by Sears, Roebuck and Co., Chicago."

LIBELED: 4-18-61, N. Dist. Calif.

CHARGE: 402(a)(2)(C)—when shipped, the article contained folic acid, a food additive, which is unsafe within the meaning of 409 since it and its use or intended use were not in conformity with a regulation or exemption in effect pursuant to 409; 403(a)—the label statement "a dietary supplement fortified with elements to aid red blood cell formation," was false and misleading, since the article was not adequate and effective for such purpose; 403(a)—the label statements "Each capsule supplies 250 mg. of liver, rich source of B-complex factors" and "The liver in this product is a source of other members of the B-Complex" were false and misleading, since the article contained an insignificant amount of liver for special dietary use; and 403(a)—the label statement "Vitamin E * * * The need for this substance in human nutrition has not been established" was false and misleading since it was contrary to fact.

DISPOSITION: 1-10-62. Default—destruction.

28196. Coconut (dietary) and cake icing. (F.D.C. No. 46907. S. Nos. 30-212 T, 30-215 T, 30-258 T.)

QUANTITY: 3 100-lb. bags and 26 cases, 10 6-oz. bags each, of coconut; and 213 cases, 40 cards of 4 tubes each, of cake icing, at Los Angeles, Calif., in possession of Service Foods.

SHIPPED: (Coconut) 7-28-61, from Manila, P.I.; and (cake icing) 9-18-61, from London, England.

LABEL IN PART: (Bag) "* * * Imported from Xamboanga * * * COCONUT DIETETIC Minimum Net Wt. 6 Oz. * * * Service Foods—Los Angeles 18, Calif." (card) "BUTTER CREAM STYLE CAKE ICINGS Simply Snip end Off Tip and Squeeze Gently To Decorate or Write on Cake Ingredients: * * * Veg. Fat. * * * Net Wt. 1 Oz. Happy House, Los Angeles 18. California—Product of England."