

erals, amino acids, and enzymes to fortify body cells to an amazing degree; and to rehabilitate weary and worn body cells; and that the article would provide a perfect, proper and complete nutritive balance to the diet; and 403 (j)—the article purported to be and was represented as a food for special dietary uses by reason of its vitamin and mineral content and its use as a means of regulating the intake of fat and carbohydrates and calories, and its label failed to bear, as required by regulations, a statement of the proportions of the minimum daily requirement for niacin, calcium, phosphorus, iron and iodine supplied by such food when consumed during a period of one day, and the percent by weight of fat and available carbohydrates in such food, and the number of calories supplied by a specified quantity of such food.

DISPOSITION: 6-22-60. Default—destruction.

26796. Multivitamin tablets. (F.D.C. No. 44587. S. Nos. 33-832/3 R.)

QUANTITY: 3 cases, each containing 71,000 Bioseal tablets, and 72 unlabeled 50-tablet btl., 168 unlabeled 100-tablet btl., 48 labeled 50-tablet btl., and 72 labeled 100-tablet btl., of Bio-Tol tablets at New York, N.Y.

SHIPPED: 2-25-60 and 3-7-60, from South Hackensack, N.J., by Batt Pharmaceutical Co., Inc.

LABEL IN PART: (Case) "S.F. 608 Contents Special Formula Tablets," and (48 and 72 btl. lots) "Bio-Tol Improved Multi-Vitamin Formula with 10 mcgm. B-12. Biopharma, Incorporated, New York 12, N.Y."

ACCOMPANYING LABELING: 1,000 loose labels reading in part "100 Viseals Bio-seals Improved Multi-Vitamin Formula * * * Biopharma, Incorporated, New York 12, N.Y." for use in labeling the tablets in the 3-case lot after repacking them into bottles; and 1,000 loose "Bio-Tol" labels.

RESULTS OF INVESTIGATION: The Bio-Tol tablets had been shipped in bulk containers and after receipt by the dealer were repacked into the above-described bottles. Analysis showed that the Bioseal tablets contained approximately 73 percent of the declared amount of vitamin B₁ and approximately 84 percent of the declared amount of vitamin C, and that the Bio-Tol tablets contained approximately 70 percent of the declared amount of vitamin C.

LIBELED: 5-27-60, S. Dist. N.Y.

CHARGE: Bioseal tablets, 402(b) (1)—while held for sale, the valuable constituents, vitamin C and vitamin B₁, had been in part omitted or abstracted from the article; 403(a)—while held for sale, the label statement "Thiamin Hcl 3 Mg. * * * Ascorbic Acid 50 Mg." was false and misleading as applied to an article containing less than the declared amounts of those vitamins; 403(a)—when shipped and while held for sale, the label statements (case) "The need in human nutrition for * * * Niacinamide has been established, but the amount required has not as yet been fully determined" and (repack bottle label) "The need for the remaining ingredients has not been established" were false and misleading since the need in human nutrition for niacinamide and the minimum daily requirement for niacinamide have been established; and 403(j)—when shipped and while held for sale, the article purported to be and was represented as a food for special dietary uses and its label failed to bear, as required by regulations, a statement of the proportion of the minimum daily requirement for niacinamide supplied by such food when consumed in a specified quantity during the period of one day. Bio-Tol tablets, 402(b) (1)—while held for sale, the valuable constituent, vitamin C, had been in part omitted or abstracted from the article; 403(a)—

while held for sale, the label statement "vitamin C (Ascorbic Acid) 30 mg." was false and misleading as applied to an article containing less than the declared amount of vitamin C; 403(a)—while held for sale, the name of the article "Bio-Tol Improved Multivitamin Formula" was false and misleading since the article contained ingredients, including minerals, in addition to vitamins; and the label statement "The need for the remaining ingredients in human nutrition has not been established" was false and misleading since the need in human nutrition for potassium, copper, magnesium, tocopherol, and methionine in the article has been established.

DISPOSITION: 7-14-60. Consent—claimed by Cosmos Chemical Corp., New York, N.Y., and released under bond for relabeling.

26797. 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 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: 403(a)—when shipped, the labeling of the articles contained statements which represented and suggested that the articles were foods for special dietary uses by reason of their lecithin content, which statements were false and misleading since the articles were of no value for such purposes; 403(a)—the names of the articles and the label declarations of the amounts of the ingredients contained in the articles were misleading since such names and declarations suggested and implied that all ingredients of the article were nutritionally significant, whereas the ingredients in the articles were not all nutritionally significant; and 403(a)—the name of the article "Soya Liquid Lecithin" was false and misleading since there is no product which may properly be designated by that name.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices.

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