

article of drug that was misbranded or adulterated in a number of specified ways, and any article of food:

(a) That purported to be, and was represented as, a food for special dietary use and was adulterated in that a valuable constituent had been in whole or in part omitted or abstracted therefrom; or

(b) That purported to be, and was represented as, a food for special dietary uses and was misbranded in that its labeling was false and misleading in particulars concerning its vitamins, minerals, and other dietary properties.

The decree further perpetually restrained and enjoined the defendants from, directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, any article of food or drug unless a number of specified manufacturing safeguards were established and maintained, and representatives of the Food and Drug Administration were given free access to various specified records and controls, including those embodying the safeguards for interstate commerce necessary for the maintenance of current good pharmaceutical manufacturing practice.

29690. Dried comfrey leaf and comfrey tablets. (F.D.C. No. 49378. S. No. 31-776 X.)

QUANTITY: 74 4-oz. bags of dried comfrey leaf, and 17 96-tablet boxes of comfrey tablets, at Riverside, Calif.

SHIPPED: On an unknown date, from Otorohanga, New Zealand, by Comfrey Supplies (N.Z.) Ltd.

LABEL IN PART: (Bag) "Vitamin Nimativ Dried Comfrey Leaf * * * Analysis * * * Mineral * * * Vitamin B Group * * * Manufactured by Comfrey Supplies (N.Z.) Ltd. * * * Otorohanga, N.Z." (box) "Comfrey Tablets Energy Strength Health * * * Recommended Dose * * * Standard Analysis * * * Mineral * * * Vitamin B Group Comfrey Supplies (N.Z.) Ltd."

ACCOMPANYING LABELING: Brochures entitled "Comfrey The Wonder Plant."

LIBELED: 10-1-63, S. Dist. Calif.

CHARGE: 403(j)—when shipped, the articles purported to be and were represented as food for special dietary use by reason of their vitamin and mineral content and their labels failed to bear as required by regulations, a statement of the proportion of the minimum daily requirement for vitamins A, B₁, C, D, riboflavin, niacin or niacinamide, and calcium, phosphorus, iron or iodine supplied by the articles when consumed in a specified quantity during the period of 1 day.

The libel alleged also that the articles were misbranded under the provisions of the Act relating to drugs as reported in notices of judgment on drugs and devices, No. 7802.

DISPOSITION: 11-15-63. Default—destruction.

29691. Dextra Sugar. (F.D.C. No. 45698. S. No. 14-996 R.)

QUANTITY: 224 cases, of 12 3-lb. bags each, at Hamilton, Ohio.

SHIPPED: 2-2-61, from Delray Beach, Fla., by Sugarlogics World Corp.

LABEL IN PART: (Bag) "New! Dextra Sugar Fortified with Vitamins and Minerals 27 Health Building Nutrients White—Granulated Packed with Health Power for the Entire Family! * * * Dextra Gives You These Nutritional Benefits! * * * A Product of The Sugarlogics World Corporation Manufactured and Distributed in Florida by The Sugarlogics Southern Corpo-

ration, Delray Beach, Florida," (tag) "Dextra Sugar Saves You Money on Essential Vitamins and Minerals! Gives You Abundant Health Benefits As You Eat!"

RESULTS OF INVESTIGATION: Analysis showed that the article was approximately 97.4 percent sucrose.

LIBELED: 4-6-61, S. Dist. Ohio.

CHARGE: 403(a)—when shipped, the name of the article was false and misleading since it suggested and implied that the article was dextrose; the labeling contained false and misleading representations that the article contained 27 health-building nutrients in natural form; that the need in human nutrition for all the substances added to the sugar has been established; and that all such substances were present in nutritionally significant amounts for special dietary use; and that by consuming the article a completely balanced diet would result; and 403(j)—the article purported to be and was represented as a food for special dietary uses by reason of its vitamin, mineral, and other dietary properties and its label failed to bear, as required by regulations, (a) a statement of the proportions of the minimum daily requirement for vitamins A, B₁, C, D, riboflavin, and niacin or niacinamide, and minerals calcium, phosphorus, iron, or iodine supplied by such food when consumed in a specified quantity during a period of one day; (b) a statement of the quantity of vitamins B₆, B₁₂, E, D, choline, inositol, betaine, and pantothenic acid, and the minerals phosphorus, sodium, silicon, manganese, magnesium, potassium, sulfur, copper, and zinc in a specified quantity of such food; (c) the statement "The need for choline, inositol, pantothenic acid, betaine, silicon, manganese, sulfur and zinc in human nutrition has not been established" and (d) a statement of the percent by weight of protein, fat, and available carbohydrates in such food and the number of available calories supplied by a specified quantity of such food.

The libel alleged also that the article was misbranded under the provisions of the Act relating to drugs, as reported in notices of judgment on drugs and devices, No. 7824.

DISPOSITION: 5-8-61. Default—delivered to a charitable institution.

29692. Soybean lecithin capsules and Sea Spray salt. (F.D.C. No. 46577. S. Nos. 39-287 T, 40-484/5 T.)

QUANTITY: 15 bulk drums of sea salt; 124 4-oz. cans of Sea Spray salt; and 18 ctns., each containing 24 100-capsule btls., 10 ctns., each containing 12 500-capsule btls., of Soybean lecithin capsules, at Valley Stream, N.Y., in possession of Barth Levitt Products, Inc.

SHIPPED: Between 6-12-61 and 10-23-61, from Houston, Tex., and Newark, N.J.

LABEL IN PART: (Drum) "Natural Mineral Sea Salt 'Nature's Own Sea Minerals'"; (can) "Natural Sea Spray Salt with Trace Elements * * * Distributed by Barth Levitt Products, Valley Stream, N.Y."; (btl.) "8 Grains Barth's Soy Bean Lecithin * * * Each capsule contains 8 grains of Soybean Lecithin * * * Distributed by Barth Levitt Products Valley Stream, N.Y."

ACCOMPANYING LABELING: Catalogs entitled "Barth's of Long Island Guide to Health Autumn [or "Mid-Summer"] Issue," and repack labels for Sea Spray salt.

RESULTS OF INVESTIGATION: The catalogs had been printed on order of the dealer and were used in promoting sales of the articles. The bulk sea salt had been repacked in part by the dealer as Sea Spray salt.