

1245. Misbranding of Bio-Mineral. U. S. v. George Aristotle and Michel N. Manteris (Bio-Mineral Products Co.). Pleas of guilty. George Aristotle fined \$750 and placed on probation for 2 years; Michel Manteris fined \$250 and placed on probation for 1 year. (F. D. C. No. 10569. Sample No. 3044-F.)

On November 22, 1943, the United States attorney for the Eastern District of Michigan filed an information against George Aristotle and Michel N. Manteris, trading as the Bio-Mineral Products Co., Detroit, Mich., alleging shipment on or about December 21, 1942, from the State of Michigan into the State of Missouri of a quantity of Bio-Mineral which was misbranded.

Analysis of the article disclosed that it consisted essentially of a water solution containing per U. S. gallon: Iron sulfate, 3,546.0 grains; magnesium sulfate $.7H_2O$, 458.6 grains; calcium sulfate, 52.0 grains; phosphate as sodium phosphate, 26.9 grains; and a minute amount of aluminum sulfate.

The article was alleged to be misbranded (1) because of false and misleading statements, together with designs illustrating a healthy colon and an abnormal colon, borne on a poster accompanying the article, which represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of rheumatism, constipation, weak kidneys, ailments of the colon leading to serious complications, piles, colitis, and appendicitis; that it would keep the colon clean and healthy by eliminating accumulated poisonous matter; that it was recommended by the medical profession generally; and that it was a solution of life-giving minerals; (2) in that the name "Bio-Mineral" was misleading since it created the impression that the article, when taken as directed, would supply the mineral elements necessary to life, whereas, when taken as directed, the article would not supply the mineral elements necessary to life; (3) in that the statement, "A natural mineral aid to be taken as a supplement for mineral deficiency," borne on the label, was false and misleading since the statement represented and suggested that the article, when used in accordance with the directions, "Half teaspoonful, or less * * * before breakfast and before retiring," would supply the user with sufficient amounts of the essential minerals to be of value in the treatment of conditions resulting from mineral deficiency, whereas the article contained, with the exception of iron, insignificant and inconsequential amounts of minerals; and (4) in that its labeling was misleading since it failed to reveal the fact that, with the exception of ferric sulfate, the article contained insignificant and inconsequential amounts of the ingredients declared in the labeling, which fact was material in the light of the following statement on the label: "Contains approximately—in gr. per. U. S. gallon: Free (uncombined Sulphuric Acid 879. Ferric Sulphate ($Fe\ 2(SO_4)_3$) 3834. Aluminum Sulphate ($Al\ 2(SO_4)_3$) 59. Calcium Sulphate ($Ca\ SO_4$) 177. Magnesium Sulphate ($Mg\ SO_4\ 7H_2O$) 800. Phosphoric Acid (as Sodium Phosphates) 145. ($Na\ 2HPO_4$) Water 52517—Total 58411 Gr."

It was also alleged in the information that, after the shipment of the article, the defendants offered to supply the consignee with certain literature; that, in response to an order from the consignee, the defendants shipped, on or about January 18, 1943, a number of envelopes, each containing a circular entitled "Important Message"; that thereafter, and while the article was held for sale by the consignee, the defendants, by means of the consignee and its employees, caused a number of the envelopes and circulars to be placed with and to accompany the article; and that these acts of the defendants resulted in the article being misbranded by reason of certain false and misleading statements in the circulars and envelopes, together with designs showing a healthy colon and, by contrast, various abnormal conditions of the colon. These statements and designs represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of constipation, acid indigestion, bloating, sourness, bad breath, indisposition, common headaches, frequent colds, common stomach disorders, a tired feeling, weak kidneys and getting up nights, decaying teeth, weak eyes, nervousness, a tired, lazy feeling, poor vision, lumbago, and acid in the stomach; that the article would restore ruined, weak, sick human bodies; that it would give the user pep, good appetite, rosy color, and zeal to work; that it would add years to one's life; that it would be efficacious in the treatment of rheumatism, infantile paralysis, gall stones, and stomach and kidney ailments; that it would be efficacious to rid the colon of waste that had been collecting, probably for years, like rust in an iron pipe; that it would bring about better health, cause the bowels to become regular, cause black, hard waste to break from the walls of the colon, produce three normal eliminations daily, like a healthy child, and cause the user to become free of the effects of constipation, gas toxins, etc.; that it would cause small pieces of white stone, threads, and crystal-like

matter to pass in the urine; that it would enable one to eat any food desired; that it would improve digestion; that it was an appropriate treatment in general for mineral deficiency diseases and for weak back, paleness, circles under the eyes, bladder trouble, arthritis, neuritis, sciatica, leg pains, and stiff or swollen joints; that it was a drugless road to health; that it would be efficacious in the prevention of weak, run-down organisms which prepare the ground for tuberculosis, cancer, nephritis, heart disease, appendicitis, piles, asthma, goiter, and rheumatism; that it would produce the benefits ordinarily ascribed to and associated with consumption of the waters of mineral springs; that it possessed rejuvenating properties; that it would give one a healthy color; and that it would be efficacious in the prevention of goiter.

On May 8, 1944, the defendants entered pleas of guilty, and on September 7, 1944, the defendant Aristotle was fined \$750 and committed for 1 year, and the defendant Manteris was fined \$250 and committed for 6 months. The prison sentences were suspended, and Aristotle was placed on probation for 2 years and Manteris for 1 year.

1246. Adulteration and misbranding of Sea-Soi, and misbranding of various other drugs. U. S. v. 91 Bottles of West's Imported Sea Vegetable Tablets, etc. Consent decree of condemnation. Products ordered released under bond for relabeling. (F. D. C. Nos. 9608, 9900. Sample Nos. 13926-F to 13935-F, incl., 14804-F, 14811-F to 14816-F, incl., 14820-F to 14827-F, incl.)

On March 29 and May 12, 1943, the United States attorney for the Southern District of California filed libels against the following products, located at Los Angeles, Calif., and packed in bottles of various sizes: 130 bottles of West's Imported Sea Vegetable Tablets; 223 bottles of Sea Vegecene (Powder); 226 bottles of Ocean Lax Tablets; 140 bottles of Sodeom Tablets; 63 bottles of Sea-V-Aid Tablets; 118 bottles of Sea-Vo-Kra tablets; 116 bottles of Imported Sea Vegetables Vitaminized with added Vitamin 'A,' in tablet form; 99 bottles of FYA Tablets; 201 bottles of D-X Tablets; 16 bottles of Sea-Soi; and 78 bottles of Kalseom Tablets. It was alleged in the libels that the articles had been shipped between the approximate dates of February 17, 1942, and January 23, 1943, by Mineralized Foods, Inc., Baltimore, Md.

Examination of West's Imported Sea Vegetable Tablets disclosed that they contained seaweed; and that they yielded approximately 29.5 percent inorganic constituents, including, per tablet, 1.2 milligrams of iodine, 43 milligrams of calcium, 6 milligrams of magnesium, 17 milligrams of phosphorus, and 0.3 milligram of iron. The article was alleged to be misbranded because of false and misleading statements on the bottle label and in a circular entitled, "West's Imported Sea Vegetables," which represented, suggested, and implied that there exists in the ordinary foods consumed a substantial deficiency in the mineral elements supplied by the article, which deficiency would result in the various disease conditions named and suggested in the labeling, i. e., arteriosclerosis, apoplexy, high blood pressure, premature aging, intestinal catarrh or inflammation, constipation, some forms of eye trouble, skin eruptions, sensitive nerves, irritability, bad temper, a listless, tired feeling, kidney diseases, rheumatism, arthritis, neuritis, tardy glandular functioning, slow child growth, goiter, thyroid disturbances, dry skin and falling hair, anemia, faulty metabolism, poor teeth, delayed coagulation of blood, rickets, weak bones, stiff joints, hardening of the arteries, acidosis, faulty elimination, and diuresis; that use of the article would prevent or correct those disease conditions; and that the article was of nutritional and therapeutic value because of the presence of sodium, potassium, and magnesium.

Examination of the Sea Vegecene (Powder) disclosed that it consisted essentially of a mixture of dried and powdered seaweed, containing, in each level teaspoonful (2.35 grams), approximately 3 milligrams of iodine, 1.5 milligrams of iron, and 4.0 milligrams of phosphorus. It was alleged to be misbranded because of false and misleading statements on its label which represented and suggested that the article was of nutritional significance because of the presence of iron, sodium, and phosphorus, as well as other unnamed minerals.

Examination of the Ocean-Lax disclosed that it consisted essentially of dried plant material including rhubarb and seaweed; and that it yielded, per tablet, approximately 0.3 milligram of iodine. It was alleged to be misbranded because of false and misleading statements on the jar label and in a circular entitled, "Are You Occasionally Constipated?", which represented, suggested, and implied that the article was appropriate for food purposes; that its laxative ingredients were derived from the ocean; that the alkalinity and amount of minerals supplied by the article were consequential; and that the use of the article as directed would be effective in the prevention of simple goiter, arteriosclerosis, apoplexy, and high