

**5793. Misbranding of Formula 8—12 Vitamins—Minerals. U. S. v. 30 Dozen Bottles of Formula 8—12 Vitamins—Minerals. Default decree of condemnation and destruction. (F. D. C. No. 9393. Sample No. 32614-F.)**

On February 24, 1943, the United States attorney for the Southern District of Indiana filed a libel against 30 dozen bottles of the above-described product at Indianapolis, Ind., alleging that the article had been shipped in interstate commerce within the period from on or about January 10 to 14, 1943, by the Universal Products Co. from Cleveland, Ohio. The article was labeled in part: "Formulas 8—12 Vitamins—Minerals Contains Soy Bean Meal, Wheat Embryo, Gum Karaya, Brewer's Yeast, Kaolin, Kelp, Activated Ergosterol, Natural Vitamin A Ester, Thiamin Hydrochloride, Riboflavin, Dicalcium Phosphate, Iron Bihydrogen, Potassium Iodide and Oil of Orange."

The article was alleged to be misbranded in that statements which appeared on the label which represented and suggested that the article was of significant nutritional value by reason of the presence therein of Vitamin E, Vitamin B<sub>6</sub>, and other factors of the B complex as found in brewer's yeast and the elements, potassium, sulfur, sodium, magnesium, copper, zinc, chlorine, and manganese were false and misleading since the product was not of significant value by reason of the presence therein of such vitamin factors and elements.

It was alleged to be misbranded further in that representations in the labeling that consumption of the product would insure normal functioning of the brain, eye, pituitary gland, parathyroid gland, thymus, heart, liver, and gall bladder, stomach and digestive system, gastro-intestinal tract, pancreas, suprarenals and adrenals, kidneys, bladder, gonads, prostate, nerves, arteries, veins, lymphatics (blood and blood vessels), muscles, bones, joints, ligaments, tendons, marrow, pineal gland, the ear, eye, spinal cord, spleen, hair, teeth and gums, thymus, lungs, mammary gland, regenerative system (ovary, placenta, prostate-gonads, etc.), and the nails; and that the article would be efficacious in the treatment or prevention of colds, infections of the lungs, formation of kidney stones and infections, the formation of bladder stones, cystitis, and other bladder infections, muscular spasms, cramps, exhaustion, inflammation and paralysis, ulcer of the eye, conjunctivitis, cataract, and night blindness, scaliness, dryness, paleness of the skin and various skin sores, gum infections, scurvy and loose teeth; and that it would be efficacious to promote health and cause the hair to become glossy and healthy were false and misleading since consumption of the article would not insure normal functioning of the various organs of the body as represented and would not be efficacious in the treatment or prevention of the various disease conditions mentioned and suggested.

The article was also alleged to be misbranded under the provisions of the law applicable to drugs reported in drugs and devices notices of judgment, No. 944.

On April 22, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**5794. Misbranding of Spark-O-Life. U. S. v. 418 Packages of Spark-O-Life. Decree of destruction. (F. D. C. No. 9197. Sample No. 2547-F.)**

On or about January 20, 1943, the United States attorney for the Western District of Missouri filed a libel against 418 packages, each containing 24 ounces, of Spark-O-Life at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about January 6, 8, 11, and 13, 1943, from Kansas City, Kans., by Spark-O-Life Co.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that the article was pure, undulterated wheat embryo (germ); that, when taken as recommended, it was of important nutritional significance because of its content of riboflavin, vitamin E, magnesium, calcium, and iron; that it was effective in preventing or overcoming fatigue, lack of stamina, constipation, joint pains, and various types of nervous and digestive diseases; that it was effective to promote health and build new energy; and that a boxful of the article contained all of the wheat germ which would be derived from 750 pounds of wheat, or the total quantity of wheat produced on 1 acre of rich wheat land, were false and misleading since the article was a mixture of wheat germ, wheat bran, and wheat flour; the riboflavin, vitamin E, magnesium, calcium, and iron content of the article was not of important nutritional significance; the article was not effective in preventing or overcoming the conditions mentioned, and would not promote health and build

new energy; and 1 boxful of the article did not contain the amount of wheat germ represented or suggested.

It was alleged to be misbranded further in that it purported to be and was represented as a food for special dietary use by reason of its content of vitamin B<sub>1</sub>, riboflavin, vitamin E, phosphorus, magnesium, calcium, and iron, and its label failed to bear such information concerning its vitamin, mineral, and other dietary properties as has been determined to be, and by regulations prescribed as necessary in order fully to inform purchasers as to its value for such uses, since its label did not state the proportion of the minimum daily requirement of vitamin B<sub>1</sub> and riboflavin, phosphorus, calcium, and iron contained in a specified quantity of the food which was customarily or usually consumed during a period of 1 day; it did not state the amount of vitamin E contained in a specified quantity of the food and that the need for vitamin E in human nutrition has not been established; and it did not state the quantity of magnesium contained in a specified amount of the food.

On March 22, 1943, no claimant having appeared, the court entered its findings that the product was misbranded and adjudged and decreed that "the findings and judgment herein extend to, and include, the name, Spark-O-Lifé, as it is written and printed upon the container cans (packages) described in the libel filed herein, with the other writings found to be effective as a misbranding of the product in question, it being the finding and the judgment of the court that such said name is not a name common, or usual, or practicable, to describe products such as is described generally on the label which is quoted in the said libel." The court further ordered that the product be destroyed.

**5795. Misbranding of Allen's Nijara Capsules. U. S. v. 16 Dozen Packages and 71 Boxes of Allen's Nijara Capsules. Decrees of condemnation and destruction. (F. D. C. Nos. 9707, 9739. Sample Nos. 37143-F, 37149-F.)**

This product consisted of dried green stem and leaf material, including in 1 lot such material as parsley and watercress, and in the other lot a considerable proportion of tissues resembling parsley. Examination of a sample showed that it contained not more than 5 U. S. P. units of thiamine (about  $\frac{1}{60}$  the minimum daily requirement of thiamine), and but an inconsequential amount, if any, of ascorbic acid, riboflavin, nicotinic acid and vitamin D.

On March 25 and April 2, 1943, the United States attorney for the District of Columbia filed libels against 16 dozen packages and 71 boxes of Allen's Nijara Capsules at Washington, D. C., alleging that the article, which had been consigned by the Allen Products Co., Inc., Washington, D. C., on or about February 24 and March 23, 1943, was in interstate commerce; and charging that it was misbranded. It was labeled in part: (Packages and boxes) "Twenty (20) Capsules Allen's Nijara Composed of the following ingredients only: Asparagus, Parsley, Watercress, Broccoli. For Adults: Suggested Daily Dosage: Five (5) capsules daily."

The article was alleged to be misbranded in that the statements appearing in its labeling, in the leaflet entitled "Allen's Nijara," attached to the packages and boxes containing the article, which represented and suggested that the article was effective to soothe pain, provide relief from rheumatism, arthritis, neuritis, sciatica, gout, lumbago, and sinusitis; that it would supply a mineral deficiency in the diet and provide pain relief from rheumatic disorders; that it was effective more quickly in the treatment of mild cases of the symptoms and diseases mentioned than in cases of long standing; and that, when taken in accordance with the directions, it would supply the body with its needs for such important minerals as calcium and phosphorus, with such important vitamins as thiamine, riboflavin, ascorbic acid, nicotinic acid, and vitamin D, were false and misleading since it was not so effective and would not supply the body with its needs for the minerals and vitamins mentioned.

It was alleged to be misbranded further in that it purported to be and was represented as a food for special dietary uses by reason of its vitamin and mineral content, and its label failed to bear such information regarding its vitamin and mineral properties as has been determined to be and by regulations prescribed as necessary in order fully to inform purchasers as to its value for such uses, since its label failed to bear a statement of the dietary properties upon which such uses were based, including the presence or absence of specific essential minerals and vitamins; and in that the statement, "only fresh vegetables are used in compounding Allen's Nijara," appearing in its labeling, was false