

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND
MISLEADING CLAIMS**

DRUGS FOR HUMAN USE*

2865. Misbranding of Paba-Liv Tablets; Toco-E Capsules; Sodium, Okra, and Celery Tablets; Amino Acids Capsules; Food Minerals Dietary Supplement; Bone Meal Tablets; 20-to-1 Liver Concentrate with Iron Capsules; Multa Vitamin Spheroid Capsules; Lecithin Capsules; Choline Chloride Tablets; B-P-D Tablets; High Potency Vitamin C Tablets; and Russian Radish and Parsley Concentrates Tablets. U. S. v. Sawall Nutritional Products, Inc. (Sawall Health Products, Inc.), and Frank A. Sawall. Pleas of nolo contendere. Fine of \$2,250 against corporation; sentence suspended against individual and individual placed on probation for 2 years. (F. D. C. No. 25612. Sample Nos. 87669-H to 87676-H, incl., 18062-K to 18070-K, incl.)

INFORMATION FILED: April 25, 1949, Eastern District of Michigan, against the Sawall Nutritional Products, Inc., formerly trading as Sawall Health Products, Inc., Detroit, Mich., and Frank A. Sawall, president of the corporation.

ALLEGED SHIPMENT: On or about March 16, 1947, and April 19, 1948, from the State of Michigan into the States of Indiana and New York.

LABEL, IN PART: "Sawall's Paba-Liv Tablets Each tablet contains: 100 Mgms. Para-Amino Benzoic Acid, 7 grs. (20-1) Liver Concentrate"; "Capsules Sawall's Toco-E * * * Each three minim capsule contains wheat germ oil and mixed natural tocopherols, equivalent in biological activity to 5 International Units or 5 Mg. Alpha Tocopherol"; "Sawall's Sodium, Okra and Celery Each tablet contains: 160 Milligrams of Dehydrated Okra, 160 Milligrams of Dehydrated Celery, 60 Milligrams of Sodium Malate"; "Capsules Sawall's Amino Acids Each capsule contains the ten essential Amino Acids in the following proportions: Lysine 10 Milligrams, Leucine 9 Milligrams, Phenylalanine 7 Milligrams, Valine 7 Milligrams, Threonine 6 Milligrams, Methionine 6 Milligrams, Isoleucine 5 Milligrams, Histidine 4 Milligrams, Tryptophane 3 Milligrams, Arginine 3 Milligrams. These are suspended in a base of 40% Protein (derived from Soy Beans), di-calcium phosphate and pepsin"; "Sawall's Food Minerals Dietary Supplement Is a composition of Minerals comprising: Calcium Carbonate, Sodium Chloride (iodized), Calcium Phosphate, Iron Sulphate, Magnesium Sulphate, Sodium Silicate, Potassium Citrate, Sodium Phosphate, Calcium Chloride, Manganese Citrate, Sulphur"; "Tablets Sawall's Bone Meal Three Tablets Daily furnish: Calcium (Ca), 1 Gram, * * * Phosphorus (P), 450 Milligrams"; "Capsules Sawall's 20-to-1 Liver Concentrate with Iron Each capsule contains 7 grains 20-1 Liver Concentrate and 20 Milligrams of Iron Reduced by Hydrogen"; "Capsules Sawall's Multa Vitamin Spheroid Capsule Each Capsule Contains: Vitamin A (Natural Ester) 5000 USP Units, Vitamin B-1 (Thiamin Chloride) 500 USP Units, Vitamin B-2 (Riboflavin) 3000 USP Micrograms, Vitamin C (Ascorbic Acid) 600 USP Units, Vitamin D (Activated Ergosterol) 1000 USP Units, Calcium Pantothenate (Dextrorotatory) 1000 Micrograms, Niacin Amide USP 10,000 Micrograms, Vitamin

*See also Nos. 2851, 2856-2860, 2863, 2864.

B-6 (Pyridoxine Chloride) 100 Micrograms, Wheat Germ Oil (Equivalent from Concentrate) Approx 160,000 Micrograms (160 Mg.) as a natural source of Vitamin E"; "Capsules Sawall's Lecithin * * * Each capsule contains: 4 Grains Soy Bean Lecithin Suspended in 3 minim pure soybean oil"; "Tablets Sawall's Choline Chloride Each tablet contains 50 Mg. Choline Chloride, 50 Mg. Inositol, 10 Mg. Methionine, in a base of 225 Mg. Liver Concentrate, and 150 Mg. DiCalcium Phosphate"; "B-P-D Tablets Each Tablet Contains: Bile Salts 1 gr., Duodenum Substance 2 grs., Pancreas 2 grs., Papaya Enzyme 2 grs., Vitamin B-1, 333 USP"; "Tablets Sawall's High Potency Vitamin C Each tablet contains: 1200 U.S.P. Units (60 Mg.) Vitamin C (Ascorbic Acid)"; and "Tablets Sawall's Russian Radish And Parsley Concentrates Each Enteric Coated Tablet Contains Russian Radish Concentrate (*Raphanus Nigra*) 6½ Grains, Parsley Concentrate 2 Grains."

NATURE OF CHARGE: *Paba-Liv Tablets, Toco-E Capsules, Sodium, Okra, and Celery Tablets, Amino Acids Capsules, Food Minerals Dietary Supplement, Bone Meal Tablets, 20-to-1 Liver Concentrate with Iron Capsules, Multa Vitamin Spheroid Capsules, and Lecithin Capsules.* Misbranding, Section 502 (a), certain statements in the accompanying labeling of the articles, namely, in a letter dated April 19, 1948, addressed to the consignee, were false and misleading. The statements represented and suggested that the articles when used as directed would be effective to overcome sterility and prevent miscarriage, whereas the articles would not be effective for such purposes.

Food Minerals, Dietary Supplement, Sodium, Okra, and Celery Tablets, Choline Chloride Tablets, B-P-D Tablets, Multa Vitamin Spheroid Capsules, 20-to-1 Liver Concentrate with Iron Capsules, High Potency Vitamin C Tablets, and Russian Radish and Parsley Concentrates Tablets. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the articles, namely, on a circular headed "A Corrective Diet Suggestion," were misleading since the articles when used as directed would not be efficacious for the purposes, and would not fulfill the promises of benefits, stated and implied. The statements represented and suggested:

That the *Food Minerals Dietary Supplement* would be efficacious in the cure, mitigation, treatment, and prevention of brain and nerve disorders, fatigue, anemia, excitability, stupidity, poor teeth and bones, retarded growth, skin diseases, poor development of hair, nails, bones, and teeth, distressing toxic conditions of the stomach and nerves, flightiness, heart trouble, muscular soreness, dental caries, infections, loss of hair, poor complexion, skin infection, poor eyesight, low endurance, nerve disorders, depression, weakness, constipation, irregular heart beat, poor muscular coordination, liver trouble, poor digestion, loss in body weight, digestive troubles, acidity, irritability, deafness, catarrh, pallor, restlessness, starvation, bloating, painful joints, albuminuria, poor water retention, brooding, sleeplessness, pallid complexion, neurasthenia, goiter, worry, erratic heart, shyness, brain collapse, sterility, overweight, deformed body, lowered mental activity, sensitiveness to infections, autointoxication, hysteria, fussiness, spastic colitis, convulsions, dilation of blood vessels, confusion of mind, lack of elasticity, nerve collapse, weak respiration of tissues, growth below normal, coldness, poor nutrition, extreme leanness, laxness, growths, forgetfulness, unsightly flesh, and creepy nervous system; that the article would promote bodily cleansing, give tone to life, firmness to arteries, and strength to pulse; that it would give endurance, long life, and will power; that it would prevent premature death, and promote alkalinity, optimism, and speed; that it would immunize against tuberculosis, cancer, and nerve exhaus-

tion; that it would give energy, lustrous hair, and bright eyes; that it would heal injuries, reduce pain, balance the body and brain, and cleanse and alkalize the body; that it would keep proportions of body, maintain normal heart action, and give vitality, warmth, magnetism, creative power, and mental endurance; that it would insure a healthy complexion, protect the brain from toxins, cool and relax the body, and give to the nervous system control and recuperation; that it would enable the fibers of the brain to connect and to coordinate thoughts; and that it would adapt the nervous system to darkness.

That the *Sodium, Okra, and Celery Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of loss of body weight, digestive troubles, nerve disorders, acidity, weakness, irritability, deafness, catarrh, pallor, restlessness, starvation, depression, infections, constipation, irregular heart heat, poor muscular coordination, liver trouble, poor digestion, bloating, painful joints, fear, albuminuria, poor water retention, loss of hair, poor complexion, skin infection, poor eyesight, low endurance, sleeplessness, autointoxication, hysteria, fussiness, spastic colitis, convulsions, dilation of blood vessels, skin diseases, retarded growth, poor development of hair and nails, distressing toxic conditions of the stomach and nerves, confusion of mind, lack of elasticity, nerve collapse, weak respiration of tissues, growth below normal, poor appetite, lowered resistance to infections, lack of vitality, respiratory troubles, sinus troubles, intestinal disorders, kidney ailments, skin troubles, frequent colds, poor teeth, weakened adrenal gland functioning, muscular weakness and fatigue, and drying up of tissues; that the article would promote bodily cleansing, give tone to life, promote alkalinity, optimism, and speed, and immunize against tuberculosis, cancer, and nerve exhaustion; that it would give energy, lustrous hair, and bright eyes; that it would heal injuries, reduce pain, and balance the body and brain; that it would cleanse and alkalize the body, keep calcium from hardening around the joints and the arteries, and cleanse and keep proportions of body; that it would give normal heart action, cool and relax the body, and give the nervous system control and recuperation; that it would enable the fibers of the brain to connect or to coordinate thoughts; that it would adapt the nervous system to darkness; that it would promote growth and maintain resistance to infections; that it would promote normal glandular functioning, especially for adrenal glands, lengthen the life span, and tone up the entire body; that it would maintain in good condition the membranes of the eyes and the membranes of the digestive tract and urinary tract; and that it would keep the skin in good condition;

That the *Choline Chloride Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of flightiness, anemia, heart trouble, muscular soreness, dental caries, poor development of bones and teeth, brain and nerve disorders, fatigue, excitability, stupidity, poor teeth and bones, retarded growth, brooding, sleeplessness, pallid complexion, irritability, neurasthenia, starvation, confusion of mind, lack of elasticity, nerve collapse, weak respiration of tissues, growth below normal, poor functioning of mammary and adrenal glands, poor cell respiration, lack of vigor, weight loss, paralysis of intestines, nervous breakdown, cataracts, loss of hair, skin trouble, lowered general tone, nerve disturbances, mouth soreness, nausea, urinary pigmentation, constipation, skin diseases, vomiting, insanity, and tongue redness; that the article would give firmness to the arteries and strength to the pulse; that it would give endurance, long life, and will power; that it would prevent premature death, insure a healthy complexion, and give vitality, warmth, magnetism, creative power, and mental endurance; that it would enable the fibers

of the brain to connect and to coordinate thoughts; that it would adapt the nervous system to darkness; that it would prevent premature old age, promote growth, improve general health, and lengthen the life span; that it would develop a healthy skin, protect against cataracts, produce better nerve tissues, and promote better assimilation; and that it would maintain normal functioning of the gastrointestinal tract and the skin;

That the *B-P-D Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of flightiness, anemia, heart trouble, muscular soreness, dental caries, poor development of bones and teeth, loss in body weight, digestive troubles, nerve disorders, weakness, acidity, irritability, deafness, catarrh, pallor, restlessness, starvation, depression, constipation, irregular heart beat, poor muscular coordination, liver trouble, poor digestion, painful joints, fear, albuminuria, poor water retention, brain disorders, fatigue, excitability, stupidity, poor teeth and bones, retarded growth, autointoxication, sleeplessness, hysteria, fussiness, spastic colitis, convulsions, dilation of blood vessels, confusion of mind, lack of elasticity, nerve collapse, weak respiration of tissues, growth below normal, poor appetite, lowered resistance to infections, lack of vitality, respiratory troubles, sinus troubles, intestinal disorders, kidney ailments, skin troubles, frequent colds, weakened adrenal gland functioning, muscular weakness and fatigue, drying up of tissues, general weakness, poor nutrition, sterility, poor glandular functioning, paralysis, lack of child growth, lack of appetite, neuritis and other nerve ailments, heart disturbances, too fast development of the thyroid, pituitary, and gonad glands, tiredness, defective teeth, poor knitting of bones, headaches, weakened blood capillaries, digestive troubles leading to gastric ulcers, weakened functioning of mammary glands, swollen limbs, hemorrhages, adrenal gland dysfunctioning, poor assimilation of calcium and phosphorus, lack of muscle tone, disintegration of teeth, deterioration of blood vessels, lack of vigor, enlarged joints, bone infection, curvature of the spine, poor functioning of mammary and adrenal glands, poor cell respiration, lack of vigor, paralysis of the intestines, nervous breakdown, cataracts, loss of hair, skin trouble, and lowered general tone; that the article would give firmness to the arteries and strength to the pulse; that it would give endurance, long life, and will power; that it would prevent premature death, cleanse and alkalinize the body, and keep calcium from hardening around the joints and in the arteries; that it would heal injuries, reduce pain, balance the body and the brain, keep the proportions of the body, maintain normal heart action, and cool and relax the body; that it would give the nervous system control and recuperation, enable the fibers of the brain to connect and to coordinate thoughts, and adapt the nervous system to darkness; that it would promote growth and maintain resistance to infections; that it would promote normal glandular functioning, especially for the adrenal glands, lengthen the life span, and tone up the entire body; that it would maintain in good condition the membranes of the eyes and the membranes of the digestive tract and urinary tract; that it would keep the skin in good condition, stimulate the appetite and assimilation, promote normal nerve functioning, and destroy acids caused by tiredness; that it would promote normal glandular functioning, especially of the reproductive, adrenal, pituitary, and thymus glands; that it would promote growth of good teeth, destroy bacterial toxins, promote better blood circulation in the capillaries, and protect the blood vessels; that it would prevent ulcers, improve the appetite, stimulate growth, and prevent infections that cause certain types of chronic arthritis; that it would promote good body form, strong bones, and normal teeth; that it would improve the general

health, prevent serious loss of phosphorus and calcium, prevent premature old age, and develop a healthy skin; and that it would produce better nerve tissues and promote better assimilation;

That the *Multa Vitamin Spheroid Capsules* would be efficacious in the cure, mitigation, treatment, and prevention of loss in body weight, digestive trouble, nerve disorders, weakness, acidity, irritability, deafness, catarrh, pallor, restlessness, starvation, brain disorders, fatigue, anemia, excitability, stupidity, poor teeth and bones, retarded growth, poor appetite, lowered resistance to infections, lack of vitality, respiratory troubles, sinus troubles, intestinal disorders, kidney ailments, skin troubles, frequent colds, weakened adrenal gland functioning, muscular weakness and fatigue, drying up of tissues, general weakness, poor nutrition, sterility, convulsions, poor glandular functioning, paralysis, lack of child growth, lack of appetite, neuritis and other nerve ailments, heart disturbances, constipation, too fast development of thyroid, pituitary, and gonad glands, painful joints, tiredness, defective teeth, poor knitting of bones, headaches, poor resistance to infections, weakened blood capillaries, digestive troubles leading to gastric ulcers, weakened functioning of mammary glands, swollen limbs, hemorrhages, adrenal gland dysfunctioning, brittle and soft bones, bow legs, low or high blood calcium, poor assimilation of calcium and phosphorus, lack of muscle tone, disintegration of teeth, deterioration of the blood vessels, lack of vigor, enlarged joints, bone infections, curvature of the spine, impotence, loss of ambition, gradual lack of muscular functioning, degenerative diseases of the nervous system, poor functioning of the mammary and adrenal glands, poor cell respiration, paralysis of the intestines, nervous breakdown, cataracts, loss of hair, skin troubles, lowered general tone, mouth soreness, nausea, urinary pigmentation, skin disease, vomiting, insanity, and tongue redness; that the article would cleanse and alkalize the body, keep calcium from hardening around the joints and in the arteries, promote growth, and maintain resistance to infections; that it would promote normal glandular functioning, especially for the adrenal gland; that it would lengthen the life span and tone up the entire body; that it would maintain in good condition the membranes of the eyes and the membranes of the digestive tract and urinary tract; that it would keep the skin in good condition, stimulate the appetite and assimilation, promote normal nerve functioning, and destroy acids caused by tiredness; that it would promote normal glandular functioning, especially of the reproductive, adrenal, pituitary, and thymus glands; that it would promote the growth of good teeth, destroy bacterial toxins, promote better blood circulation in the capillaries, and protect the blood vessels; that it would prevent ulcers, improve the appetite, and stimulate growth; that it would prevent infections which cause certain types of chronic arthritis, promote good body form, strong bones, and normal teeth, and prevent serious loss of phosphorus and calcium; that it would prevent miscarriages, improve general health, prevent premature old age, and develop a healthy skin; and that it would produce better nerve tissues, promote better assimilation, and maintain normal functioning of the gastrointestinal tract and the skin;

That the *20-to-1 Liver Concentrate with Iron Capsules* would be efficacious in the cure, mitigation, treatment, and prevention of brooding, sleeplessness, pallid complexion, irritability, neurasthenia, starvation, confusion of mind, lack of elasticity, nerve collapse, weak respiration of the tissues, growth below normal, poor functioning of mammary glands, poor cell respiration, lack of vigor, weight loss, paralysis of the intestines, nervous breakdown, cataracts, loss of hair, skin trouble, lowered general tone, nerve disturbances, mouth soreness,

nausea, urinary pigmentation, constipation, skin disease, vomiting, insanity, and tongue redness; that the article would insure a healthy complexion, give vitality, warmth, magnetism, creative power, and mental endurance, and enable the fibers of the brain to connect and to coordinate thoughts; that it would adapt the nervous system to darkness, improve general health, promote growth, prevent premature old age, lengthen the life span, and develop a healthy skin; that it would produce better nerve tissues and promote better assimilation; and that it would promote general health and maintain normal functioning of the gastrointestinal tract and the skin;

That the *High Potency Vitamin C Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of painful joints, tiredness, defective teeth, poor knitting of bones, headaches, poor resistance to infections, weakened blood capillaries, restlessness, digestive troubles leading to gastric ulcers, weakened functioning of mammary glands, swollen limbs, hemorrhages, paralysis, sterility, and adrenal gland dysfunctioning; that the article would promote growth of good teeth, destroy bacterial toxins, promote better blood circulation in the capillaries, and protect the blood vessels; that it would prevent ulcers, improve the appetite, and stimulate growth; and that it would prevent infections which cause certain types of chronic arthritis;

That the *Russian Radish and Parsley Concentrates Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of loss of body weight, digestive troubles, nerve disorders, weakness, acidity, irritability, deafness, catarrh, pallor, restlessness, starvation, depression, constipation, irregular heart beat, poor muscular coordination, liver trouble, poor digestion, bloating, painful joints, fear, albuminuria, and poor water retention; that the article would cleanse and alkalize the body and keep calcium from hardening around the joints in the arteries; that it would heal injuries, reduce pain, and balance the body and brain; and that it would keep the proportions of the body and maintain normal heart action.

DISPOSITION: July 13, 1949. Pleas of nolo contendere having been entered, the court imposed a fine of \$2,250 against the corporation, suspended sentence against the individual, and placed him on probation for 2 years.

2866. Misbranding of Retisol Compound. U. S. v. 11 Bottles * * *. (F. D. C. No. 26660. Sample No. 51266-K.)

LABEL FILED: March 21, 1949, Eastern District of Kentucky.

ALLEGED SHIPMENT: On or about February 1 and March 2, 1949, from Cincinnati, Ohio.

PRODUCT: 11 12-ounce bottles of *Retisol Compound* at Covington, Ky., in the possession of the King Drug Co., Store #8. There were on display in the store 4 copies of a newspaper advertisement, clipped from a Cincinnati newspaper by employees of the store. One copy was pasted on each of the two front windows and one on each of the two cash registers in the store.

LABEL, IN PART: "Retisol Compound An efficient alkaline compound containing: Sodium salicylate, sodium citrate, potassium acetate, and hexamethylene."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the newspaper advertisement were false and misleading since the article was not effective in the treatment of the following conditions, stated and implied: "Rheumatic Sufferers Arthritic Sufferers Throw Away Your Canes! Retisol is Here * * * Learn how Retisol has helped people like you, people who have spent torturous days and nights nursing your inflamed bodies of fiery red,