

On March 30, 1943, no appearance, responsive affidavit, or pleading having been filed, the court ordered that the defendant, his agents, servants, and employees, and all other persons in active concert or participation with him, be permanently enjoined and restrained from directly or indirectly introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce the article sold under the name Korjena, as then labeled, in violation of the Federal Food, Drug, and Cosmetic Act.

**907. Misbranding of Korjena. U. S. v. Jerome V. Gladke (Korjena Medicine Co.).**  
**Plea of guilty. Fine, \$200.** (F. D. C. No. 5517. Sample Nos. 19250-E, 19370-E.)

On December 16, 1941, the United States attorney for the Western District of New York filed an information against Jerome V. Gladke, trading as the Korjena Medicine Co., Elmira, N. Y., alleging shipment on or about September 18, 1940, and January 10, 1941, from the State of New York into the State of Pennsylvania of a quantity of Korjena which was misbranded.

Analysis of a sample of the article showed that it contained phenolphthalein, compounds of calcium and magnesium, iodides, bile salts, and extracts of plant drugs including a strychnine-bearing drug.

The article was alleged to be misbranded in that the statements, "A Dependable Treatment for the Reduction of Excessive Fat \* \* \* This Treatment is Guaranteed Dependable and may be taken with Complete Confidence \* \* \* Especially in overweight cases of long standing these tablets should be faithfully taken regularly as directed. Two or three packages are usually required for the best results \* \* \* This Treatment is dependable in normal conditions \* \* \* All normal cases of excessive weight may confidently follow above directions," borne on the boxes containing the article, were false and misleading since they represented and suggested that the article was a dependable, safe, and adequate treatment for the reduction of excessive fat, whereas it was not a safe, dependable or adequate treatment for such purpose but might produce harmful results. The article was alleged to be misbranded further in that the statement, "Active Ingredients: Phenolphthalein, Calcium Iodide, Sodium Choleinate," borne on the boxes, was false and misleading since the said statement represented and suggested that phenolphthalein, calcium iodide, and sodium choleinate were the only active ingredients, whereas the article contained the active ingredient strychnine in addition to those named; in that it was not designated solely by a name recognized in an official compendium, and was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of strychnine contained in it; in that its label failed to bear adequate directions for use since the directions, "Take 1 tablet after each meal \* \* \* Especially in overweight cases of long standing these tablets should be faithfully taken regularly as directed. Two or three packages are usually required for the best results," were not suitable and appropriate directions for the drug, which was essentially a laxative; in that its labeling did not bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since it was a cathartic or laxative and contained phenolphthalein and should not be used when abdominal pain, nausea, vomiting or other symptoms of appendicitis are present, and frequent or continued use might result in dependence on laxatives, and that it should be discontinued if a skin rash should appear

On December 28, 1942, the defendant having entered a plea of guilty, the court imposed a fine of \$200.

**908. Adulteration and misbranding of Bullock's System Self Treatment for Sinus and Catarrhal Infection. U. S. v. Henry Spangler (National Laboratories, Inc.).** **Plea of nolo contendere. Sentence of 180 days in jail conditionally suspended.** (F. D. C. No. 7209. Sample No. 50930-E.)

This product, which was packed in a cardboard container, consisted of one can of Bullock's Antiseptic Healing and Cleansing Tonic, one jar of Bullock's Nasal Salve, one box of Bullock's Clear Head Tablets, one vial of Sneeze-It, and one bottle each of King Cold Knockout, Ear Oil, Special Sea Salt, and Bullock's Antiseptic Emollient, and a device which included a nasal atomizer of the common variety, an aluminum can with hose connection for irrigating the sinus, a measuring cup, and a thermometer.

On August 19, 1942, the United States attorney for the District of Columbia filed an information against Henry Spangler, trading as National Laboratories, Inc., Washington, D. C., alleging shipment within the period from on or about January 1 to March 1, 1941, from the District of Columbia into the State of Maryland of the above-described products which were misbranded, and portions of which were adulterated.

Analysis of the Antiseptic Healing and Cleansing Tonic showed that it consisted essentially of sodium bicarbonate, sodium chloride, and a small proportion of potassium iodide. Bacteriological examination showed that the article failed to kill *Staphylococcus aureus* at 37° C. and 45° C. in the concentration recommended (1 heaping tablespoonful in 2 quarts of water), or in 10 times that concentration.

The article was alleged to be misbranded in that the statements in the labeling which represented that when used singly or with the device the article was an antiseptic and a healing and cleansing tonic for the nasal cavities; that it was a safe and efficacious treatment of both chronic and acute cases of nasal sinus and catarrhal infection; that it would reduce the inflammation of the membrane and tissue of the nasal cavities; that it would soothe, heal, and refresh the nasal cavities in cases of sinus infection; that it would give strength to the eyes and eyesight; that it would be efficacious in the treatment of hay fever and chronic head colds, and in the treatment of the membrane tissue of the bowel and colon; that it would keep the head cavities clear of mucus and poisonous secretions; that, when weakened as directed, it would be efficacious in the treatment of nasal diseases in persons who have had nasal operations or where the tissues are particularly sensitive; that it would be efficacious in the treatment of the dry form of catarrh and of acid catarrh, and thereby remove the cause of sores in the cavity regions, especially in the nostrils; that it would be invaluable in the treatment of colds and would control the common cold completely; that its use would avoid suffering, save time and obviate costly operations, clear up infection, reduce inflammation, heal irritation, antisepticize the infected part, remove foul pus, mucus, and secretions, and sterilize the infected and diseased parts; that it would automatically cause inflammation of the membrane to subside, and remove obstructions from the mouth of the sinuses and produce a normal drainage; that it would produce immediate relief in cases of acute attacks of sinus and would cure chronic sinus and prevent blindness and deafness by curing sinus diseases; that the article was a complete cure for colds in the head, and would save human life, improve the hearing and promote sleep; that it was a permanent cure for sinus diseases and headaches, would remove from the system poisons caused by sinus infections, and would prevent pneumonia and other serious ills, were false and misleading since it was not an antiseptic and would not accomplish the results claimed.

The article was alleged to be misbranded further in that it was in package form and its label failed to bear an accurate statement of the quantity of contents.

The Antiseptic Healing and Cleansing Tonic was also alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to be an antiseptic, whereas it was not an antiseptic within the meaning of the law in that it was not a germicide when used in the dilutions recommended in the labeling thereof, and did not purport to be, and was not represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

Analysis of the Antiseptic Emollient showed that it consisted essentially of hexylresorcinol, glycerine, and water colored with a green dye. Bacteriological examination showed that the article was not antiseptic and germicidal. It was alleged to be misbranded in that the statements in the labeling which represented that when, used singly or with the device it was an antiseptic and germicide and would be efficacious in the cure, mitigation, treatment or prevention of nasal sinus were false and misleading, since it was not an antiseptic or germicide and would not be efficacious for the said purpose.

Analysis of the Nasal Salve showed that it consisted essentially of menthol and camphor incorporated in a base of white petrolatum. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it was efficacious in the cure, mitigation, treatment, or prevention of nasal sinus, and would protect the membrane and tissue from irritation; that it had healing qualities and was efficacious in the treatment of the

dry form of catarrh, stubborn cases of catarrh and acid catarrh that cause sores in a cavity region; and that it was efficacious in clearing the walls of the throat of tight clinging secretion and in clearing blocked eustachian tubes were false and misleading since it would not be efficacious for the purposes represented.

Analysis of the Clear Head Tablets showed that they contained acetanilid 0.90 grain per tablet, sodium salicylate, quinine hydrochloride, and cascara sagrada. They were alleged to be misbranded in that the statements appearing in their labeling which represented and suggested that the tablets were efficacious in the cure, mitigation, treatment or prevention of feverish condition, temperature, headaches, and severe pain resulting from sinus infection, and would provide quick relief in cases of severe sinus pains and headaches were false and misleading since they were not efficacious for such purposes, and would not provide a quick relief in such cases. They were alleged to be misbranded further in that their labeling failed to bear adequate directions for use since the directions upon the label did not provide for any limitation as to the quantity of the tablets to be administered; and in that their label failed to bear adequate warnings against use by children, or in those pathological conditions wherein their use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users since, by reason of the presence of acetanilid in the tablets, frequent or continuous use might be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the tablets, and not more than the recommended dosage should be taken, and they should not be given to children.

Analysis of the King Cold Knockout showed that it consisted essentially of sodium bicarbonate, alcohol, and oil of peppermint. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it was efficacious in the cure, mitigation, treatment, or prevention of common colds; that it would dissolve congestion due to common colds by chemical reaction through the chemistry of the body; that it was harmless to the system and would neutralize cold congestion and thereby avoid acute attacks of sinus were false and misleading since it was not harmless to the system and would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of alcohol contained in the article.

Analysis of the Ear Oil showed that it consisted essentially of menthol and camphor in a solution of olive oil. It was alleged to be misbranded (1) in that the statements appearing in the labeling which represented and suggested that it would be a safe and effective treatment for ear trouble resulting from sinus or catarrhal infection were false and misleading since it would not be a safe and effective treatment for such purpose; and (2) in that its label failed to bear an accurate statement of the quantity of the contents of the article.

Analysis of the Special Sea Salt showed that it consisted essentially of approximately 95 percent of sodium chloride and slightly more than 1 percent of potassium iodide. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of sinus and catarrh if used as directed, and would be a valuable assistant in connection with the treatment of chronic sinus and hay-fever were false and misleading since it would not be efficacious or a valuable assistant for the purposes recommended. It was alleged to be misbranded further in that it was in package form and its label failed to bear an accurate statement of the quantity of contents.

Analysis of the Sneeze-It showed that it consisted essentially of camphor and ground-up plant material such as ginger or capsicum. It was alleged to be misbranded in that the statements appearing in its labeling which represented and suggested that it would create normal functioning of the membrane tissue, would aid to throw off disease, would aid in obtaining speedy results in stubborn and obstinate cases of sinus trouble, and would assist in removing congestion were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further (1) in that it was in package form and its label failed to bear the name and place of business of the manufacturer, packer, or distributor; and (2) its label failed to bear an accurate statement of the quantity of the contents.

The antiseptic Healing and Cleansing Tonic, Antiseptic Emollient, Clear Head Cold Tablets, Ear Oil, Special Sea Salt and Sneeze-It were alleged to be mis-

branded further in that they were not designated solely by names recognized in an official compendium, and each was fabricated from two or more ingredients and the label of each failed to bear the common or usual names of the active ingredients and, in the case of the Clear Head Cold Tablets, failed to bear a statement of the quantity or proportion of acetanilid present.

The device was alleged to be misbranded in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, particularly the labeling for Bullock's Antiseptic Healing and Cleansing Tonic, and the statements contained in the circular entitled "Directions for use of Bullock's System Home Treatment."

On January 12, 1943, the defendant having changed his original plea of not guilty to a plea of *nolo contendere*, the court imposed a sentence of 180 days in jail, which was suspended on condition that the defendant was not then selling and would not again engage in the sale of the articles and the device complained of in the information.

**909. Misbranding of Dr. Peter's Kuriko. U. S. v. Dr. Peter Fahrney & Sons Co. Plea of *nolo contendere*. Fine, \$250. (F. D. C. No. 6435. Sample No. 60224-E.)**

The labeling of this product bore false and misleading therapeutic claims and failed to give adequate directions and warnings for use.

On May 12, 1942, the United States attorney for the Northern District of Illinois filed an information against Dr. Peter Fahrney & Sons Co., a corporation, Chicago, Ill., alleging shipment on or about May 15, 1941, from the State of Illinois into the State of Washington of a quantity of a drug, known as Dr. Peter's Kuriko, which was misbranded.

Analysis showed that this drug consisted of a brown liquid containing chiefly plant extractives, emodin-bearing drugs, sugars, water, and alcohol.

The article was alleged to be misbranded in that the statements regarding its efficacy in the cure, mitigation, treatment, or prevention of disease appearing in the labeling were false and misleading since they represented and suggested that the article was a stomachic and would be efficacious in strengthening the stomach or stimulating its action; that it was a diuretic; that it was efficacious in the cure, mitigation, treatment, or prevention of nervousness, indigestion, and upset stomach, headaches, loss of sleep and appetite, and common colds; that it would produce an excellent effect upon the general state of health and would help the body eliminate waste products by way of the kidneys; that it would aid digestion in the stomach and intestines and thus prepare all foods for use in the body; that it would aid digestion in the intestines by preventing faulty elimination and thus help the entire digestive function, and would remove waste products from the blood and from the tissues of the body; that the drug was efficacious in the cure, mitigation, treatment or prevention of a general feeling of poor health; that it would act on the bowels without griping or purging, and would effectively remove gas and irritating waste matter from the stomach; that it was essential to good health; that it would prevent the many disorders which arise from constipation, such as headache, malaise, nervousness, irritability, and loss of appetite; that it would prevent nervous conditions caused by distress signals arising from the nerve endings in the lower bowel; that it would prevent the serious illnesses resulting from common colds by preventing a run-down condition caused by faulty elimination; that it was efficacious in the cure, mitigation, treatment or prevention of nervousness and weakness following a surgical operation; and that it would improve the appetite, cure nervous indigestion, promote sleep, aid the stomach to function, and regulate the bowels, whereas the article was not a stomachic nor a diuretic, and it was not essential to good health and would not be efficacious, with respect to the other matters as described above.

The article was alleged to be misbranded further in that the label failed to bear adequate directions for its use since the directions did not provide a limitation for the duration of its administration; and in that the label failed (1) to warn that the article should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and (2) that the frequent or continued use of the article might result in dependence upon a laxative and, by reason thereof, the label did not bear such adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users.