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United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the Food and Drugs Act]

30601-30650

DRUGS

[Approved by the Acting Secretary of Agriculture, Washington, D. C., September 20, 1939]

30601. Adulteration and misbranding of Dr. Koch's Sept-O-Cide and Dr. Koch's Cold Tablets and misbranding of Dr. Koch's Stick Salve, Dr. Koch's Inhalo, Dr. Koch's Camph-O-Lin, Dr. Koch's Cough Syrup, Dr. Koch's Vegetable Tea Tablets, Dr. Koch's Dyspepsia Tablets, Dr. Koch's Mentho-Campho, and Dr. Koch's Liver Pills. U. S. v. Koch Products Co. Pleas of guilty. Sentence deferred. Cases dismissed by court when defendant called for sentence. (F. & D. Nos. 38600, 38631. Sample Nos. 63231-B, 63237-B to 63241-B, inclusive, 5172-C to 5175-C, inclusive.)

The labeling of these products, with the exception of the cold tablets, bore false and fraudulent representations regarding their curative and therapeutic effects; and that of the Sept-O-Cide bore false and misleading representations regarding its antiseptic, germicidal, and sterilizing properties. The cold tablets contained less acetanilid than the amount declared.

On January 25, 1938, the United States attorney for the District of Minnesota, acting upon reports by the Secretary of Agriculture, filed in the district court two informations against the Koch Products Co., a corporation, Winona, Minn., alleging shipment by said defendant in violation of the Food and Drugs Act as amended, within the period from on or about July 2, 1935, to on or about June 29, 1936, from the State of Minnesota into the State of Wisconsin, of quantities of the above-named drug preparations which were misbranded and certain of which were also adulterated.

Analyses showed that the Stick Salve consisted essentially of a small proportion of zinc oxide incorporated in a base containing rosin and beeswax; that the Sept-O-Cide consisted essentially of small proportions of zinc chloride, volatile oils including menthol and thymol, formaldehyde, vanillin, saccharin, alcohol (22.7 percent by volume), glycerin, and water; that the Inhalo consisted essentially of volatile oils, including eucalyptol and menthol (32.5 percent by volume), alcohol (53.4 percent by volume), and water; that the Cold Tablets contained less than 2½ grains of acetanilid each, namely, not more than 1.95 grains of acetanilid each; that the Campho-Lin consisted essentially of turpentine, small proportions of camphor, soap, ammonia, and ammonium chloride, and water; that the Cough Syrup consisted essentially of small proportions of ammonium chloride, volatile oils including menthol and oil of anise, and extracts of plant drugs including licorice, chloroform (0.09 gram per 100 cubic centimeters), sugar, and water; that the Mentho-Campho was a white powder consisting chiefly of sucrose and small amounts of menthol, camphor, and starch; that the Vegetable Tea Tablets contained plant drugs including licorice, sassafras, and an emodin-bearing drug, calcium carbonate, and sugar; that the Dyspepsia Tablets contained small proportions of bismuth subcarbonate, calcium carbonate, charcoal, and sugar; and that the Liver Pills contained extracts of

plant drugs including aloe, nux vomica, and an emodin-bearing drug, coated with sugar and lime carbonate.

The Stick Salve was alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that it was effective as a cure and remedy for cuts, sores, rheumatic pains, neuralgic pains, rheumatism, backache, etc.

The Sept-O-Cide was alleged to be adulterated in that its strength and purity fell below the professed standard and quality under which it was sold, (bottle) "Sept-O-Cide" and (circular) "A * * * very effective antiseptic and germicide"; whereas it was not an antiseptic and germicide when used as directed on the label. It was alleged to be misbranded in that the statements in the labeling, (bottle) "Sept-O-Cide Alcohol 15%" and (circular) "Sept-O-Cide * * * an excellent combination for sterilization and germicidal purposes * * * to be employed wherever its purifying and germ-destroying properties are required * * * Dr. Koch's Sept-O-Cide is a * * * very efficient antiseptic and germicide * * * Sept-O-Cide a liquid antiseptic," and "For sterilizing and deodorizing purposes in sick room use Sept-O-Cide full strength," were false and misleading since the article contained 22.7 percent by volume of alcohol, was not an antiseptic and germicide when used as directed on the label, and would not be effective at any strength for sterilizing. It was alleged to be misbranded further in that certain statements in the labeling falsely and fraudulently represented that it was effective to tend to harden the gums, to guard the human system against contagious disease, to cure sore, spongy, or bleeding gums, tender mouth, certain inflamed mucous membranes of the mouth and throat, tonsillitis, pyorrhea, stomatitis, and other superficial disorders of the teeth and the mouth; and effective as a douche in nasal catarrh and to keep one well.

The Inhalo was alleged to be misbranded in that it contained 53.4 percent of alcohol by volume, but neither the bottle label nor the carton bore a statement of the quantity or proportion of alcohol contained in the article. It was alleged to be misbranded further in that certain statements in the labeling falsely and fraudulently represented that it was effective to relieve head, throat, and nose congestion and the discomfort of nasal catarrh; to relieve congestion of the passages of the head, nose, and throat; to prevent the spread of inflammation and infection of the membranes of the head, nose, and throat; and to relieve difficult breathing, sore throat, running nose, and nasal catarrh.

The Cold Tablets were alleged to be adulterated in that their strength and purity fell below the professed standard and quality under which they were sold in that the bottle label bore the statement "Each tablet contains 2½ grains acetanilide"; whereas each of the tablets contained not more than 1.95 grains of acetanilid. They were alleged to be misbranded in that the statement "Each tablet contains 2½ grains acetanilide," borne on the bottle label, was false and misleading.

The Camph-O-Lin was alleged to be misbranded in that the statement "Camph-O-Lin," borne on the bottle label, was false and misleading since it denoted that the article contained camphor as its principal ingredient in both quantity and strength; whereas it consisted essentially of turpentine, small proportions of camphor, soap, ammonia, ammonium chloride, and water. It was alleged to be misbranded further in that certain statements in the labeling falsely and fraudulently represented that it was effective to cure "neuralgia, bronchitis, and congestions of different nature," and effective to relieve the discomforts and pain attendant upon common swellings on the body, and as remedial in rheumatic and neuralgic pains; and as a curative of simple sore throat, lumbago, lameness due to back strain, earache, and aching feet.

The Cough Syrup was alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that it was effective in the treatment of coughs and as a remedy for la grippe, severe colds in the head and similar ailments, hoarseness and similar conditions, and as a cure for worms in children.

The Vegetable Tea Tablets were alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that the article was effective to strengthen the bowels, to aid the kidneys, to keep one in a condition of health, to cure constipation, dyspepsia, enervation, liver trouble, sallow complexion, scrofula, skin diseases, stomach pains, summer complaint, and torpid liver, to activate the kidneys, and to accelerate the cure of kidney complaint; effective for the relief of biliousness and blotches on the face;

and effective to relieve and to hasten the cure of female complaints, to relieve from ulcers, and to act as a preventive of appendicitis, catarrh, depressed spirits, diseased blood, jaundice, and vertigo or dizziness.

The Dyspepsia Tablets were alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that they were effective to cure dyspepsia, indigestion, stomach catarrh, and all complaints of the stomach, and to afford relief from indigestion, stomach catarrh, and other stomach troubles arising from indigestion or dyspepsia.

The Mentho-Campho was alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that it was effective as a cure and remedy for catarrh, hay fever, and all catarrhal affections.

The Liver Pills were alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that they were effective as a cure for all troubles from torpid and diseased liver.

On January 25, 1938, pleas of guilty having been entered on behalf of the defendant to both informations, the court announced that sentence would be deferred until the January 1939 general term of court.

At the January 1939 term sentence again was deferred until March 13, 1939, on which day the court, upon being informed that none of the products of the defendant examined by this Department since the date of the original pleas had been found subject to regulatory action, ordered that the pleas of guilty be withdrawn and that the cases be dismissed.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

30602. Misbranding of Willson's Monarch Cough Syrup, Willson's Monarch Buchu Compound, Willson's Camphor and Eucalyptus Ointment, Willson's Monarch Worm Powder, Willson's Monarch Antiseptic Dusting Powder, and Willson's Monarch Healing Salve. U. S. v. Willson Monarch Laboratories, Inc. Plea of nolo contendere. Fine, \$100. (F. & D. No. 39837. Sample Nos. 34160-C, 34161-C, 34218-C, 34219-C, 34221-C, 34222-C, 34224-C.)

The labeling of these products, including both human and veterinary remedies, bore false and fraudulent representations regarding their curative and therapeutic effects, and that of the Dusting Powder bore misleading representations regarding its antiseptic properties. The Cough Syrup contained chloroform which was not declared on the label.

On February 5, 1938, the United States attorney for the Western District of Wisconsin, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Willson Monarch Laboratories, Inc., Edgerton, Wis., alleging shipment by said defendant, in violation of the Food and Drugs Act as amended, within the period from on or about January 25 to on or about April 2, 1937, from the State of Wisconsin into the State of Illinois of quantities of the above-named drug preparations which were misbranded.

Analyses of samples showed that the Cough Syrup consisted essentially of extracts of plant drugs, pine tar, a small proportion of chloroform, glycerin, sugar, and water; that the Buchu Compound consisted of tablets containing extracts of plant drugs including buchu, and compounds of sodium and potassium; that the Camphor and Eucalyptus Ointment contained small proportions of camphor and eucalyptus incorporated in a petrolatum base; that the Worm Powder consisted essentially of plant material including areca nut, compounds of iron, magnesium, calcium and sodium, sulfates, chlorides, and carbonates; that the Antiseptic Dusting Powder consisted essentially of calcium carbonate, magnesium sulfate, small proportions of an iron compound and creosote, and talc; and that the Healing Salve was an ointment containing a small proportion of camphor incorporated in a petrolatum base. Bacteriological examination of the Dusting Powder showed that it was not an antiseptic nor a germicide, and would not serve as a germ-proof covering.

The Cough Syrup was alleged to be misbranded in that certain statements in the labeling regarding its curative and therapeutic effects falsely and fraudulently represented that it was effective for the cure and mitigation of coughs, bronchitis, croup, la grippe, whooping cough, and asthmatic and hacking cough. It was alleged to be misbranded further in that it contained chloroform and the bottle label failed to bear a statement of the quantity or proportion of chloroform that it contained.

The Buchu Compound was alleged to be misbranded in that certain statements in the labeling falsely and fraudulently represented that it was effective to