

30985. Misbranding of Cal-co-cin. U. S. v. George T. Lambert, David Periera, and George D. Lambert (Crescent-Kelvan Co.). Pleas of nolo contendere. Fines, \$250. (F. & D. No. 42713. Sample Nos. 29934-D, 34424-D, 34642-D, 34644-D, 34703-D.)

The labeling of this product bore misleading representations regarding its ingredients and false and fraudulent representations regarding its curative and therapeutic effectiveness.

On September 13, 1939, the United States attorney for the Eastern District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the district court an information against George T. Lambert, David Periera, and George D. Lambert, trading as the Crescent-Kelvan Co., a business trust, Philadelphia, Pa., alleging shipment by said defendants in violation of the Food and Drugs Act as amended, within the period from on or about June 11 to on or about October 20, 1938, from the State of Pennsylvania into the States of New Jersey and Maryland, of quantities of Cal-co-cin which was misbranded.

Analysis of a sample taken from one of the shipments showed that it contained 1.85 grains of cinchophen, 2.55 grains of benzoic acid, and 0.47 grains of calcium per capsule. Analyses of samples taken from the remaining shipments showed that they were of substantially the same composition.

The article was alleged to be misbranded in that the statement "Bi-Calcium-Ortho-Benzycin," borne on the bottle label, was false and misleading in that it purported to set forth and indicate the composition of the article; whereas the article contained compounds of cinchophen, a potentially dangerous drug, in amounts varying from 1.5 grains to 2 grains per capsule and said statement gave no indication of the presence in the article of the said compounds of cinchophen. It was alleged to be misbranded further in that the following statements in the labeling were false and misleading in that they would lead the purchaser to believe that the article was a safe and appropriate remedy for the conditions set forth therein; whereas it was not a safe and appropriate remedy for the conditions set forth in said statements but was a dangerous drug: (Bottle label in certain shipments) "For Arthritis, Rheumatoid conditions and Uric Acid Eliminant. Dosage—One capsule four times a day with a full glass of water, after meals and on retiring"; (box label in one shipment) "for Arthritis, Rheumatoid conditions and Uric Acid Eliminant"; (leaflet in one shipment) "Cal-co-cin Clinical reports received warrants us offering the Medical Profession this non-toxic, non-habit forming Chemical Combination for Arthritis, Rheumatoid Conditions and Uric Acid Eliminant Brief Summary and Treatment Rheumatism generally speaking is considered to be of infectious origin, due to various strains of the Streptococci. To understand sensitization of cells is important, for Rheumatism can affect different organs and tissues of the body—as the joints or certain group of muscles. It may also affect the throat, or even some nerve register complaint may be elicited at times. Waste products may not be eliminated properly from the cells, hence the catabolic process being on an increase in its activity. Treatment consists of destroying the various strains of Streptococci; also to free the choked or catabolic cells of their waste material, dissolve and eliminate the Uric Acid and Urates. 'Cal-co-cin' is a chemical derived by the action of Benzoic and Phenyl Cinchonic Acids on Calcium, forming a Calcium-Benzo-Phenyl Cinchonate—(Bi Calcium Ortho-Benzycin.) A Solvent for, also an eliminator of Uric Acid ($C_5H_4N_2O_3$) when the Uric Acid combines with a base and Urates are formed per se, the use of 'Cal-co-cin' for that joint condition has given most gratifying results. 'Cal-co-cin' has antiseptic value as well and is tolerated most favorably by the stomach and intestines; also the liver and Kidneys. Dr. M., Philadelphia, reports in several cases of long standing, very comfortable after one weeks treatment, one case in particular, female age 64, bedfast six weeks, after two weeks treatment with 'Cal-co-cin' very comfortable, better results than from all other medication including injections. Dr. — New Jersey, reports patient after taking fifty 'Cal-co-cin' Capsules, pain and burning had almost ceased, Uric Acid corrected so that patient did not have to get up nights. Dr. A. E. S., Phila., Pa.—used 'Cal-co-cin' in combination with 'Cholax' (Saline laxative) with excellent results, patient much relieved after few doses. Dr. R. E. G., Philadelphia, Pa.—Results from 'Cal-co-cin' very satisfactory, warrants my reordering. Dosage—We suggest one capsule with a full glass of water after each meal and on retiring, can be increased at discretion of physician with perfect safety."

The article was alleged to be misbranded further in that statements in the labeling regarding its curative and therapeutic effects falsely and fraudulently

represented that it was a safe and appropriate remedy for arthritis and rheumatoid conditions and was a safe and appropriate uric acid eliminant; whereas when used as directed, it was not a safe and appropriate treatment but was a dangerous drug in that said article was capable of causing serious, irreparable, or fatal injury to consumers.

Certain of the shipments were also alleged to be misbranded in violation of the Federal Food, Drug, and Cosmetic Act, as reported in notice of judgment No. 77 published under that act.

On December 8, 1939, pleas of nolo contendere were entered on behalf of the defendants. On January 5, 1940, the court imposed fines amounting to \$250 for violation of both acts.

GROVER B. HILL, *Acting Secretary of Agriculture.*

30986. Misbranding of Pixine Pile Remedy and Pixine Ointment. U. S. v. Fred R. Lossoe (The Pixine Co.). Plea of guilty. Fine, \$75. (F. & D. No. 42715. Sample Nos. 8371-D, 14163-D, 35784-D, 35785-D.)

The labeling of these products bore false and fraudulent representations regarding their curative and therapeutic effectiveness. The labeling of one lot of the Pixine Pile Remedy was further objectionable because of the false and misleading representations that it was guaranteed under the Food and Drugs Act.

On October 16, 1939, the United States attorney for the Northern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Fred R. Lossoe, trading as the Pixine Co., Troy, N. Y., alleging shipment by said defendant in violation of the Food and Drugs Act as amended, within the period from on or about January 18 to on or about September 8, 1938, from the State of New York into the States of Illinois and Massachusetts, of quantities of Pixine Pile Remedy and Pixine Ointment that were misbranded.

Analysis showed that the pile remedy consisted essentially of tannic acid, ichthyol, and volatile oils including turpentine, incorporated in a petrolatum and fatty acid base. Analysis of the ointment showed that it consisted essentially of volatile oils including turpentine, origanum oil, and juniper oil, and a small proportion of ichthyol, incorporated in a petrolatum and lanolin base.

One shipment of the pile remedy was alleged to be misbranded in that statements in the labeling regarding its curative and therapeutic effects falsely and fraudulently represented that it was effective as a pile remedy; effective as a treatment, remedy, and cure for internal and external piles, fistula, ulcer or fissure of anus, all inflammatory conditions of the rectum, hemorrhoids and itching, hemorrhoidal and protruding piles; and effective to give immediate relief to any form of piles, to reduce inflammation, and to relieve and cure itching and smarting of the anus. The said shipment was alleged to be misbranded further in that the statement "Fully guaranteed under the Pure Food and Drug Act," contained in a circular shipped with the article, was false and misleading in that it represented that the article had been examined and approved by the Government and that it complied with the Food and Drugs Act of June 30, 1906; whereas it had not been examined and approved by the Government and it did not comply with the said Food and Drugs Act. The remaining shipment of Pixine Pile Remedy was alleged to be misbranded in that statements in the labeling regarding its curative and therapeutic effects falsely and fraudulently represented that it was effective as a pile remedy; effective as a treatment, remedy, and cure for internal and external piles, hemorrhoids, fistula, ulcer or fissure of anus, and all inflammatory conditions of the rectum; effective to give immediate relief and to reduce inflammation; and effective as a relief for rectal ailments.

One shipment of the Pixine Ointment was alleged to be misbranded in that statements in the labeling regarding its curative and therapeutic effects falsely and fraudulently represented that it was effective as a treatment, remedy, and cure for varicose and indolent ulcers, scrofulous and inflammatory swellings, all cuts, contused and lacerated wounds, carbuncles, boils, piles, psoriasis and other inflammatory skin diseases, septic wounds, pneumonia or other inflammatory affections of the chest and abdomen, croup, congestion and inflammation of the respiratory organs, ulcers, bed sores, erysipelas, septic infection, inflammatory affections of the skin and respiratory organs, abscesses, bruised and mangled wounds, infected wounds, scaly skin diseases, eczema, and congestion of throat and chest due to colds; effective as an ideal surgical