

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

### DRUGS FOR HUMAN USE\*

**2534. Alleged misbranding of Glyoxylide, Benzoquinone, and Malonide. U. S. v. Koch Laboratories, Inc., Dr. William F. Koch, and Louis Koch (2 indictments). Pleas of not guilty. Tried to a jury. No verdict rendered because of inability of jury to agree. Cases retried before second jury, but before verdict could be rendered, illness of one of twelve jurors required discharge of the jury. Case subsequently dismissed. (F. D. C. No. 6439. Sample Nos. 7694-E to 7696-E, incl., 23632-E, 23633-E, 63479-E, 72742-E, 72745-E, 73179-E, 73183-E, 79252-E, 79621-E.)**

**INDICTMENTS RETURNED:** Between April 2 and 15, 1942, Eastern District of Michigan, against Koch Laboratories, Inc., Detroit, Mich., Dr. William F. Koch, president, and Louis Koch, secretary-treasurer.

**ALLEGED SHIPMENT:** On or about January 23 and February 2, 3, 4, 5, 6, and 19, 1942, from the State of Michigan into the States of California, Missouri, Kentucky, Indiana, and Oregon.

**LABEL, IN PART:** "Koch's Synthetic Antitoxins Glyoxylide Prepared from Aliphatic sulphonates We ascribe to it the formula OCCO Each ampoule contains approximately 2 cc. (dilution 10-12) for Allergy Cancer Infection Sold to Physicians Only"; "(Koch's Synthetic Antitoxins) \* \* \* (1:4 Benzoquinone) Koch Each ampoule contains approximately 2 cc. aqueous solution (dilution 10-6) For the Infections and Their Sequelae Sold only to Physicians"; and "(Koch's Synthetic Antitoxins) Malonide O-c-c-c-O Each ampoule contains approximately 2 cc. aqueous solution (dilution 10-12) Anti-Allergic Sold Only to Physicians."

**NATURE OF CHARGE:** Misbranding, Section 502. (a), it was alleged that certain statements on the labels of the articles were false and misleading. The statements on the respective labels represented and suggested that the *Glyoxylide* was efficacious in the cure, mitigation, treatment, and prevention of cancer, allergic conditions, and infection, and that it was efficacious as an antitoxin; that the *Benzoquinone* was efficacious in the cure, mitigation, treatment, and prevention of infections and sequelae of infections, and that it was efficacious as an antitoxin; and that the *Malonide* was efficacious in the cure, mitigation, treatment, and prevention of allergies, and that it was efficacious as an antitoxin. The indictment charged that the products would not be efficacious for those purposes.

**DISPOSITION:** Pleas of not guilty having been entered, the matter came on for trial before a jury on January 12, 1943. The trial continued to May 28, 1943, at which time the jury announced that it was unable to agree upon a verdict. Retrial of the matter was held, beginning February 20, 1946, and continuing to July 23, 1946. On this latter date the trial was ended when one of the members of the jury, then considering and deliberating upon a verdict, stated that because of illness he was unable to proceed. The Government's attorney moved the court to permit the 11 remaining jurors to continue their deliberations with a view to reaching a verdict, but because of the opposition of counsel for the defendant, the court discharged the jury. On August 17, 1948, the Government's attorney made a motion for the entry of an order of nolle prosequi, and, on the same date, the court entered an order to that effect.

**2535. Misbranding of Glancaps. U. S. v. Darnell Drug Co., Wilbur F. Darnell, and George W. Darnell. Pleas of guilty. Fine of \$250 against company and \$10 against each individual. (F. D. C. No. 24265. Sample No. 83156-H.)**

**INFORMATION FILED:** June 30, 1948, Southern District of Indiana, against the Darnell Drug Co., a partnership, Indianapolis, Ind., and Wilbur F. Darnell and George W. Darnell, partners in the partnership.

**ALLEGED SHIPMENT:** On or about July 15, 1947, from the State of Indiana into the State of Ohio.

**LABEL, IN PART:** "Glancaps \* \* \* Active ingredients: Oil of Albasantal, minims 3. Oleoresin Cubeb, minims 2. Oil of Copaiba, minims 3. Rectified Oil of Terpen, minims 2. Extract of Zea Mays, grains 5. Each capsule contains 13.3 minims."

\*See also Nos. 2502-2505, 2511-2517, 2521, 2523, 2524, 2526-2529, 2532, 2533.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the labels of the article were false and misleading, since they represented and suggested that the article would be an adequate treatment for enlarged prostate glands and kidney, bladder, and urinary irritations; that it would be efficacious in healing and cleansing the entire urinary system; and that it would eliminate urinary poisons. The article would not be an adequate treatment for the conditions represented; it would not be efficacious in the healing and cleansing of the entire urinary system; and it would not eliminate urinary poisons.

**DISPOSITION:** October 29, 1948. Pleas of guilty having been entered, the court imposed a fine of \$250 against the partnership and \$10 against each individual.

**2536. Misbranding of National R Solution. U. S. v. 18 Bottles \* \* \*. (F. D. C. No. 24950. Sample No. 26576-K.)**

**LIBEL FILED:** June 14, 1948, Eastern District of Missouri.

**ALLEGED SHIPMENT:** On or about March 11 and May 6, 1948, by the National Drug Co., from Philadelphia, Pa.

**PRODUCT:** 18 4-ounce bottles of *National R. Solution* at St. Louis, Mo. Examination showed that the product consisted essentially of a solution of zinc phenolsulfonate and potassium iodide.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the following label statements were false and misleading, since the article would not be effective for the conditions stated and implied: (Bottle label) "Indications: For use as a mild astringent application in inflammation of mucous membranes of the urethra" and (carton label) "Indications: For use as a mild astringent application in inflammation of mucous membranes."

**DISPOSITION:** July 9, 1948. Default decree of condemnation and destruction.

**2537. Misbranding of Mafoliata. U. S. v. 9 Bottles \* \* \*. (F. D. C. No. 24718. Sample No. 1024-K.)**

**LIBEL FILED:** April 16, 1948, Southern District of Florida.

**ALLEGED SHIPMENT:** On or about December 27, 1947, by the Mafoliata Corp., from Chicago, Ill.

**PRODUCT:** 9 1-quart bottles of *Mafoliata* at Coral Gables, Fla., together with a circular entitled "Ma-Ta," which was shipped with the article. Examination showed that the product consisted essentially of water, an extract of a berberine bearing drug, and a small amount of sodium benzoate.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the circular were false and misleading, since they represented and suggested that the article would be effective in the treatment of syphilis, all kinds of surface infections, athlete's foot, cuts, lacerations, burns, gonorrhea, toxic poison, eczema, psoriasis, skin eruptions, stomach ulcers, gallstones, kidney stones, ulcers of the bladder and kidneys, leg ulcers, arthritis, tumor of the brain, hay fever, asthma, sinus, acne, cancer, sciatica, thrombosis, nervous disorders, dull, pasty, iron-gray or yellow jaundice complexion, aches and pains, sleepless nights, all kinds of discomforts, constipation, piles, hemorrhoids, boils, swellings, bumps, growths, abscesses in the ear drum, carbuncles, ulcers, and germ diseases and infections. The article would not be effective in the treatment of such conditions, symptoms, and diseases.

**DISPOSITION:** May 14, 1948. Default decree of forfeiture and destruction.

**2538. Misbranding of Ball Solution. U. S. v. 216 Bottles, etc. (F. D. C. No. 24747. Sample No. 36646-K.)**

**LIBEL FILED:** May 4, 1948, Western District of Washington.

**ALLEGED SHIPMENT:** On or about January 31, 1948, by the Timball Liniment Co., from Arcadia, Calif.

**PRODUCT:** 216 bottles of *Ball Solution* at Kirkland, Wash., together with 200 circulars entitled "The Ball Solution," which were shipped with the product. Examination showed that the product consisted essentially of alcohol, water, iodine, potassium iodide, and a small proportion of methyl salicylate.

**LABEL, IN PART:** (Bottle) " \* \* \* Bone & Muscle Treatment For The Relief of Arthritis \* \* \* For the relief of arthritis apply to the painful area \* \* \* For sprains, swelling, and lameness \* \* \* When applying to the knee, cover only the front, even though the pain and swelling may be in the back of the knee. Both places will be relieved \* \* \*" and (circular)