

**LABEL, IN PART:** "Napoleons [or "Derbies"] Manufactured for Jay Dee Drug Co., Chicago, Ill., by the Killian Manufacturing Co., Akron, Ohio."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement, "for prevention of disease," was false and misleading as applied to an article containing holes.

**DISPOSITION:** December 17, 1945, and April 5, 1946. No claimant having appeared, judgments were entered ordering that the product be destroyed.

**1872. Adulteration and misbranding of prophylactics. U. S. v. 63½ Gross and 26½ Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 17517. Sample Nos. 23644-H, 23645-H.)**

**LABEL FILED:** February 25, 1946, Southern District of Texas.

**ALLEGED SHIPMENT:** On or about June 24, 1945, by the World Merchandise Exchange, from New York, N. Y.

**PRODUCT:** 90 gross of *prophylactics* at Houston, Tex. Examination of samples indicated that 5 percent of the product was defective in that it contained holes.

**LABEL, IN PART:** "Lloyd's Made from Liquid Latex," and "Silver-Tex Prophylactics."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the quality of the article fell below that which it purported to possess.

Misbranding, Section 502 (a), (portion) the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

**DISPOSITION:** April 11, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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

### DRUGS FOR HUMAN USE

**1873. Misbranding of sea water (Cal-O-Dine). U. S. v. 17 Bottles of Sea Water. Default decree of condemnation and destruction. (F. D. C. No. 17577. Sample No. 27976-H.)**

**LABEL FILED:** October 4, 1945, District of Oregon.

**ALLEGED SHIPMENT:** From Alameda, Calif., by Cal-O-Dine. The product was shipped on or about June 22, 1945, and a number of leaflets were shipped on or about February 1, 1945.

**PRODUCT:** 17 ½-gallon bottles of sea water at Eugene, Oreg., together with a number of leaflets headed "The Mysterious ingredient of sea-water." Analyses indicated that the product was sea water.

**LABEL, IN PART:** "Sea Water Sold Under Trade Name of Cal-O-Dine."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statement, "To supply trace minerals naturally occurring in sea water," was misleading since it represented and suggested that such trace minerals would have some nutritional or medicinal effect upon the user when the article was consumed in accordance with the directions upon the label, whereas those trace minerals would not have that effect, and the misleading effect of the statement was not corrected by the modifying phrase, "though in nutritionally non-significant amounts"; the label statement, "A difference in medical and nutritional opinion exists contrary to representations of value of this product. In favor of the value of trace minerals contained in sea water are the opinions of various medical and nutritional experts qualified by scientific training to evaluate," were false and misleading since there is no difference of opinion among qualified medical and nutritional experts with reference to the uselessness of sea water taken in accordance with the instructions specified on the label, either as a dietary supplement or as a remedial agent; and the entire labeling of the article was misleading in the absence of a statement of the fact, material in the light of the labeling, that the article would serve no useful purpose either as a nutritional adjuvant or as a drug when consumed in accordance with the directions on the label.

Further misbranding, Section 502 (a), the following statements in the leaflet, when read in connection with the label directions for ingestion of sea water,

\*See also Nos. 1852, 1853, 1859, 1862, 1865-1868, 1870-1872.

were misleading since they created the impression that the ingestion of sea water would serve some useful purpose, whereas ingestion of sea water would serve no useful purpose: "The Mysterious ingredient of sea-water, which must be present in addition to the salts and minerals of sea-water, has long been a subject of interest for marine biologists. The lack of this ingredient in artificial sea-water results in inability of the aquarium to support marine life. The inorganic composition of sea-water is, in general terms, similar to the composition of extracellular fluids in the body. Like the body, the ocean maintains a constant osmotic, ionic and acid-base structure and a nearly constant temperature, and it uses for these purposes the same materials as those found in the body. The concentration of the minerals in sea-water is over three times that of the blood serum."

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

**DISPOSITION:** November 6, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1874. Misbranding of Poland Water. U. S. v. 900 Bottles of Poland Water and 200 Booklets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 17745. Sample No. 2935-H.)**

**LIBEL FILED:** October 4, 1945, District of Columbia.

**PRODUCT:** 300 ½-gallon bottles, 400 1-quart bottles, and 200 12-ounce bottles of *Poland Water*, offered for sale by Magruder, Inc., at Washington, D. C., together with 200 accompanying booklets entitled "Let Me Tell You What Poland Water Can Do For You." Examination showed that the product was a slightly mineralized water.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements and designs in the booklets were false and misleading since they represented and suggested that the article would be effective in the treatment of illness regarded as incurable, pain due to gravel (uric acid calculi), stiffness of joints, kidney and bladder troubles, heart trouble, artery and kidney changes, dyspeptic troubles, any disease accompanied by hardening of tissue, scanty secretion of the kidneys, stomach ailments and digestive trouble, hepatic and renal calculi, sluggish bowel action, headache, depression, nausea, difficulties involving the functioning of the kidneys, prostate gland, or urinary passages, and albuminuria of pregnancy. The labeling further represented and suggested that the article would speed recovery in many diseases, from colds to pneumonia; that it would keep the kidneys, lungs, and pores efficient; that it would enable one to know the thrill of being fully alive, keen, alert, and ready for strenuous problems; that it would supply liquid energy; that it would assure that vital food elements would be carried to the cells; that it would insure better assimilation and elimination; that it would help the blood to repair body damage; that it would normalize the colon; and that it was an answer to health problems and would be effective to maintain health. The article would not be effective for such purposes.

**DISPOSITION:** October 25, 1945. Hiram Ricker & Sons, Poland Springs, Maine, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration.

**1875. Misbranding of lime juice. U. S. v. 1,811 Cases of Lime Juice. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 18998. Sample No. 8160-H.)**

**LIBEL FILED:** January 22, 1946, Southern District of New York.

**ALLEGED SHIPMENT:** On or about November 7, 1945, by the Seminole Fruit & Preserving Co., Inc., from Little River, Fla.

**PRODUCT:** 1,811 cases, each containing 24 bottles, of *lime juice* at New York, N. Y. A recipe sheet was wrapped around each bottle.

**LABEL, IN PART:** (Bottle label) "Cobbs Lime Juice Natural Full Strength Unsweetened Use the same as fresh fruit juice, as this is Undiluted Lime Juice No Artificial Coloring or Flavor is used. Contains ¼ of 1% Sodium Benzoate as a preservative \* \* \* Net Contents 6 Fl. Ozs."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the statement on the bottle label, "It has more important Citric Acid than any other Fruit Juice," was misleading since it suggested that the citric acid content of the article was of