

sented and implied that the article contained 8 grains of iron and ammonium citrate and 4 grains of calcium hypophosphite per fluid ounce; that it would assist the body in the formation of red blood corpuscles; that it would build weight and strength; and that it would be efficacious in the cure, mitigation, treatment, and prevention of lost appetite, indigestion, after-eating pains, gas, bloating, belching, nausea, sick headache, heartburn, constipation, biliousness, spots before the eyes, backache, loss of energy and vitality, too frequent kidney action, arm and leg pains, bad blood, bad color, boils, pimples, lost weight, stiff joints, sore muscles, rheumatism, nervousness, a tired-out feeling, colds, infection, brittle finger nails, despondency, and irritability. The article did not contain the declared proportions of iron and ammonium citrate and calcium hypophosphite; and it would not be effective to produce the benefits stated and implied.

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: May 21, 1946. No claimant having appeared, judgment of condemnation was entered and the product and circulars were ordered destroyed.

1936. Misbranding of Cal-O-Dine. U. S. v. 49 Bottles of Cal-O-Dine, and 375 Leaflets. Default decree of condemnation and destruction. (F. D. C. No. 18713. Sample No. 27869-H.)

LIBEL FILED: January 7, 1946, Western District of Washington.

ALLEGED SHIPMENT: From Alameda, Calif., by the Cal-O-Dine Laboratories. The product was shipped on or about August 17, 1945. The leaflets had been shipped on or about October 12, 1943.

PRODUCT: 49 $\frac{1}{2}$ -gallon bottles of *Cal-O-Dine* at Seattle, Wash., together with 375 leaflets entitled "The Mysterious ingredient of sea-water." Examination showed that the product consisted essentially of small proportions of calcium, iron, and iodine compounds dissolved in sea water.

LABEL, IN PART: (Leaflets) "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."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements in the leaflets quoted above, when read in connection with the directions for ingestion of sea water, (bottle label) "Directions Six teaspoonfulls (one ounce) daily, 2 with each meal in water, fruit or vegetable juice. Cal-O-Dine is scientifically designed to supplement the diet with desirable amounts of three important minerals, Calcium, Iron and Iodine and when taken as directed supplies Calcium—375 milligrams 50% minimum daily requirement Iron—10 milligrams 100% minimum daily requirement Iodine—0.1 milligrams 100% minimum daily requirement Net Contents 64 Ounces Price \$10.00," were misleading since the statements and directions created the impression that the ingestion of sea water would serve some useful purpose. The ingestion of sea water would serve no useful purpose.

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: March 25, 1946. No claimant having appeared, judgment of condemnation was entered and the product and leaflets were ordered destroyed.

1937. Misbranding of Red Hearts Tonic. U. S. v. 4½ Dozen Bottles of Red Hearts Tonic, and 300 Envelopes. Default decree of condemnation and destruction. (F. D. C. No. 19483. Sample No. 24599-H.)

LIBEL FILED: April 2, 1946, Northern District of Alabama.

ALLEGED SHIPMENT: On or about January 26, 1946, by the Reese Chemical Co., from Cleveland, Ohio.

PRODUCT: 4½ dozen bottles of *Red Hearts Tonic* at Birmingham, Ala., together with 300 envelopes entitled "If You Lack Ambition to 'Go Places and Do Things' Try Red Hearts." Examination showed that the article consisted essentially of iron sulfate with a small amount of manganese sulfate.

LABEL, IN PART: "Red Hearts Iron Manganese B₁ and E Tonic."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements and designs in the labeling of the article were false and misleading since the article would not be effective in imparting pep and ambition: (Display carton) "Gee! You're full of Pep—[cut showing older couple dancing] Of Course! He's taking Red Hearts"; (envelope) "Gee! You're full of Pep—[cut showing older couple dancing] If you Lack Ambition to 'Go Places and Do Things' Try Red Hearts * * * Try them and see if they do not make you feel wonderful."

DISPOSITION: May 2, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1938. Misbranding of Ortex Tablets and Kayon Tablets. U. S. v. 40 Bottles of Ortex Tablets and 62 Bottles of Kayon Tablets. Default decree of condemnation and destruction. (F. D. C. No. 19265. Sample Nos. 7278-H, 7279-H.)

LABEL FILED: March 8, 1946, Northern District of New York.

ALLEGED SHIPMENT: On or about October 26 and November 30, 1945, by the Berland Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 28 20-tablet bottles and 12 100-tablet bottles of *Ortex Tablets* and 31 20-tablet bottles and 31 75-tablet bottles of *Kayon Tablets* at Binghamton, N. Y. Examination showed that the products had essentially the composition stated on their labels.

LABEL, IN PART: "Ortex * * * Each Tablet Contains: Vitamin B₁ 666 U. S. P. Units Yohimbin Hydrochloride 0.005 gm Orchic Substance 0.050 gm Calcium Glycerophosphate 0.150 gm Sodium Glycerophosphate 0.150 gm," or "Kayon Tablets Each tablet contains 1/8 grain Extract Belladonna Leaves containing 0.00156 grain Total Alkaloids of Belladonna and 1/10 grain Extract Nux Vomica containing 0.00738 grains Strychnine. Also contains Methenamine. Extract Ergot, Potassium Bicarbonate and Extract Rhus Aromatica. For Adults For the temporary relief of incontinence."

NATURE OF CHARGE: *Ortex Tablets.* Misbranding, Section 502 (c), the common or usual names of the active ingredients of the article, which are required by Section 502 (e) to appear on the label, did not appear on the label in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use, since no distinction had been made in the list of ingredients between those which were active and those which were inert, such as orchic substances.

Kayon Tablets. Misbranding, Section 502 (a), the label statement, "For the temporary relief of incontinence," was false and misleading since the article would not be effective for that purpose.

DISPOSITION: April 10, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1939. Misbranding of Prostall Capsules. U. S. v. 4 Bottles of Prostall Capsules, and 50 Leaflets. Default decree of condemnation and destruction. (F. D. C. No. 19764. Sample No. 7377-H.)

LABEL FILED: May 7, 1946, District of New Jersey.

ALLEGED SHIPMENT: From Boston, Mass., by the Douglas Laboratories, Inc. The product was shipped on or about January 2, 1946, and the leaflets were shipped during the month of December 1945.

PRODUCT: 4 100-capsule bottles of *Prostall Capsules* at Plainfield, N. J., together with 50 leaflets entitled "The Story of Prostall." Analysis showed that the product consisted essentially of glutamic acid and aminoacetic acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the bottle label, and certain statements contained in the leaflet accompanying the article, were false and misleading: "Prostall 'Stalls Off Pain' * * * relieves the symptoms of prostate hypertrophy (prostitis). Relief starts in a few days and improvement continues thereafter. Prostall permanently relieves some cases. However, it is primarily a pain-reducer in time." These statements represented and suggested that the article would be effective in the relief of pain and prostate hypertrophy, whereas it would not be effective for such purposes. Further misbranding, Section 502 (e) (2), the drug was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.