NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended.

DISPOSITION: January 6, 1949. Default decree of destruction.

2604. Misbranding of Zon-A-Wave Ozone Generator. U. S. v. 12 Devices, etc. (F. D. C. No. 26003. Sample No. 32306–K.)

LIBEL FILED: December 9, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about September 8, 1948, from Portland, Oreg.

PRODUCT: 12 devices, some of which were labeled "Zon-A-Wave Ozone Generator" and others which were labeled "Portable Ozone Applicator," in the possession of Mrs. Etta H. Gehlen, San Jose, Calif., and certain other persons in Los Gatos, San Jose, and Oakland, Calif., on rental from Mrs. Gehlen. 5,000 pamphlets entitled "Ozone Health Center" and 5 display cards entitled "Pure Ozone is being generated" were also in the possession of Mrs. Gehlen. The pamphlets and display cards were printed in San Jose, on instructions of Mrs. Gehlen. Examination showed that the device was an electrical device which generated ozone.

NATURE OF CHARGE: Misbranding, Section 502 (a), the pamphlets and display cards contained statements which represented and suggested that the devices were effective in the treatment of rheumatism, sinus trouble, neuritis, colds, influenza, stomach trouble, osteomyelitis caused by scarlet fever, severe pain, cough left as an effect of pneumonia, infection, sprained ankle, lame back, varicose veins, chest colds, severe abdominal pains caused by gallstone attack, headache, sinus pains, milk leg, high fever, paralysis from multiple neuritis, continual pain, arthritis, and other kindred ailments, impurities in the blood, and ulcers; that the devices would prevent diseases including tonsillitis, sore throat, colds, headache, stomach-ache, ear-ache, tooth-ache, indigestion, fever, la grippe, and pneumonia; and that the devices would increase efficiency. The devices were not effective in the treatment of the symptoms, diseases, and conditions stated and implied; they would not prevent the diseases and conditions named; and they would not increase efficiency.

Further misbranding, Section 502 (f) (1), the devices bore no directions for use. The devices were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: December 14, 1948. Default decree of condemnation. One device and several copies of the pamphlet and display card were ordered delivered to the Food and Drug Administration, for exhibition in its museum at Washington, D. C., and the remainder of the devices, pamphlets, and display cards were ordered destroyed.

2605. Adulteration and misbranding of elixer of three bromides, tincture of opium camphorated (paregoric), syrup of potassium guaiacolsulfonate, and elixir of terpin hydrate and codeine. U. S. v. David M. Leff (Merit Laboratories Co.). Plea of nolo contendere. Fine, $700. (F. D. C. No. 25581. Sample Nos. 32–K, 33–K, 52–K, 10425–K, 15156–K.)

INFORMATION FILED: January 25, 1949, Eastern District of Pennsylvania, against David M. Leff, trading as the Merit Laboratories Co., Philadelphia, Pa.

ALLEGED SHIPMENT: Between the approximate dates of February 4 and March 2, 1948, from the State of Pennsylvania into the States of South Carolina, New York, and Michigan.

NATURE OF CHARGE: *Elixir of Three Bromides.* Adulteration, Section 501 (b), the article purported and was represented as "Three Bromides Elixir," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since each 100 cc. of the article contained less than 23 grams of total bromides, and the difference in strength of the article from the standard was not stated on its label.

Misbranding, Section 502 (a), the label statements "Elixir of Three Bromides N. F. * * * Each 100 cc Contains 8 Gm Ammoniated Bromide * * * 8 Gm Potassium Bromide * * * 8 Gm Sodium Bromide" were false and misleading since the article did not conform to the specifications of the National Formulary and each 100 cc. of the article contained less than 24 grams of bromides.

Tincture of opium camphorated (paregoric). Adulteration, Section 501 (b), the article purported to be "Camphorated Opium Tincture," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since each 100 cc. of the article yielded more than 45 mg. of anhydrous morphine and the difference in strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statement "Each fluid ounce represents Opium powdered 1.83 gr." was false and misleading since the statement represented that each fluid ounce of the article contained the therapeutically active constituent of powdered opium, namely, anhydrous morphine, in an amount not more than is present in 1.83 grains of powdered opium, whereas each fluid ounce of the article contained the therapeutically active constitutent of powdered opium in a larger amount than is present in 1.83 grains of powdered opium.

Syrup of potassium guaiacolsulfonate. Adulteration, Section 501 (b), the article purported to be and was represented as "Potassium Guaiacolsulfonate Syrup," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since each 1,000 cc. of the article contained less than 75 grams of potassium guaiacolsulfonate and the difference in the strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statement "Syrup of Potassium Guaiacolsulfonate N. F. Each 100 cc. represents Potassium Guaiacolsulfonate 7.5 gm." was false and misleading since the article did not conform to the specification of the National Formulary and each 100 cc. of the article contained less than 7.5 grams of potassium guaiacolsulfonate.

Elixir of terpin hydrate and codeine. Adulteration, Section 501 (b), the article purported to be and was represented as "Terpin Hydrate and Codeine Elixir," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained less terpin hydrate and less codeine than required by the standard and the difference in the strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statements "Elixir Terpin Hydrate and Codeine N. F. * * * Active constituents in each 100 cc. Terpin Hydrate 1.7 gms. Codeine alkaloid 0.2 gms.," were false and misleading since the article did not conform to the specifications of the National Formulary and each 100 cc. of the article contained less than 1.7 grams of terpin hydrate and less than 0.2 grams of codeine alkaloid.

Further misbranding, Section 502 (f) (1), the labeling of all of the articles failed to bear adequate directions for use since there was no statement in the labeling of any condition, disease, or function for which the articles were to be used.

DISPOSITION: February 16, 1949. A plea of nolo contendere having been entered, the court imposed a fine of $700.

2606. Misbranding of Dee-Lay Caps. U. S. v. The Duncan Co. Plea of guilty. Fine, $100. (F. D. C. No. 25564. Sample No. 20887–K.)

INFORMATION FILED: November 17, 1948, Western District of Oklahoma, against The Duncan Co., a partnership, trading under the name of the Dee-Lay Co., at Oklahoma City, Okla.

ALLEGED SHIPMENT: On or about December 30, 1947, from the State of Oklahoma into the State of Kansas.

PRODUCT: *Dee-Lay Caps.* Analysis showed that the product consisted chiefly of capsules containing camphor, ferrous sulfate, with capsicum and aloes indicated, and tablets containing calomel with plant material indicated.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Dee-Lay Caps * * * Recommended for the relief of delayed menstration caused from Colds, Nervousness or Over Exposure" was false and misleading since the article would not be efficacious in the treatment of delayed menstruation and would not be efficacious for the relief of delayed menstruation caused from colds, nervousness, and over exposure. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and the tablets of the article contained the ingredient, calomel, a derivative of mercury; and the label of the article did not bear a statement showing the substance from which the ingredient was derived and the fact that the ingredient was derived from mercury; and, further, the label did not bear a statement of the quantity or proportion of calomel contained in the tablets. Further misbranding, Section 502 (f) (2), the article was a laxative and its labeling failed to bear a warning that it should not be used when abdominal pain (stomach-ache, cramps, and colic), nausea, vomiting (stomach sickness), or other symptoms of appendicitis are present, and the labeling of the article also failed to warn that frequent or continued use may result in dependence upon laxatives to move the bowels.

DISPOSITION: January 4, 1949. A plea of guilty having been entered, the court imposed a fine of $100.

2607. Misbranding of orchic substance and spleen liquid. U. S. v. 187 Vials, etc. (F. D. C. No. 25850. Sample Nos. 7492–K, 7493–K.)

LIBEL FILED: October 14, 1948, Western District of New York; amended libel filed November 3, 1948.

ALLEGED SHIPMENT: On or about September 1, 1948, by Bruce Laboratories, Inc., from Trenton, N. J.

PRODUCT: 187 30-cc. size vials of *orchic substance* and 170 25-cc. size vials of *spleen liquid* at Buffalo, N. Y. There were no labels upon the immediate containers of the articles. In the shipping cartons were handwritten sheets bearing the following: "Control #484 Orchic Substance Ziegler order #2221 192 Total" and "Control #485 Spleen Liquid Ziegler order #2221 Total No. of Bottles 175."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the labels of the articles failed to bear the common or usual names of the articles,