

* * * Loeser Laboratory, Inc., New York, N. Y. Subsidiary Of The Wm. S. Merrell Company."

The phenobarbital sodium was alleged to be misbranded in that the statements on its labels, "Phenobarbital Sodium U.S.P. 2 Grains * * * Each ampul contains Phenobarbital Sodium, U.S.P. 0.13 Gm. (2 grs.)," and "Phenobarbital Sodium U.S.P. * * * 2 Grains," were false and misleading since the article contained phenobarbital sodium in amounts varying from 2.04 grains (0.1324 gram) to 2.78 grains (0.1800 gram).

The procaine hydrochloride was alleged to be misbranded in that the statements on its labels, "Procaine Hydrochloride, U.S.P. 50 mg. [or "100 mg.," "120 mg.," "150 mg.," or "200 mg.]," were false and misleading since the article contained the following amounts of procaine hydrochloride: 66.4 mg. to 106.3 mg. in the 50-mg. lot; 100.7 mg. to 157.6 mg. in the 100-mg. lot; 74.4 mg. to 104.8 mg. in the 120-mg. lot; 49.3 mg. to 147.4 mg. in a portion of the 150-mg. lot, and 166.3 mg. to 235 mg. in the remainder of the 150-mg. lot; and 224.8 mg. to 284.5 mg. in the 200-mg. lot.

The procaine hydrochloride was alleged to be misbranded further in that, by reason of the variance of the contents of the ampuls from the amounts declared on the labels, the article would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in its labeling, i.e., "For spinal anesthesia by admixture with spinal fluid * * * To be used only by or on the prescription of a physician."

On November 10, 1944, pleas of guilty were entered on behalf of the defendants, and on November 13, 1944, the corporate defendant was fined \$200 on each of the 7 counts, a total fine of \$1,400; imposition of sentence against the individual defendant was suspended, and he was placed on probation for 30 days.

1302. Adulteration of Eye-Gyrol and misbranding of Stero-Uteroids. U. S. v. Lloyd M. Curts and Charles D. Folse (Curts-Folse Laboratories). Pleas of guilty. Fine, \$200. (F. D. C. No. 7722. Sample Nos. 73167-E, 73170-E.)

On November 7, 1942, the United States attorney for the District of Kansas filed an information against Lloyd M. Curts and Charles D. Folse, copartners trading as the Curts-Folse Laboratories, Kansas City, Kans., alleging shipment of a quantity of the above-named products from the State of Kansas into the State of Missouri on or about August 4 and December 10, 1941.

The Eye-Gyrol was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, since it purported and was represented to contain 12½ percent of argyrol, whereas it contained argyrol in amounts varying from 4.35 percent to 8.30 percent.

Analysis of the Stero-Uteroids disclosed that the article consisted essentially of small proportions of zinc sulfate, plant material including alkaloid-bearing drugs, and a trace of iodine incorporated in a base of ichthyol and wool fat. It was alleged to be misbranded (1) in that its name, "Stero-Uteroids," the fact that it was packaged in a collapsible metal tube with key, and the directions on the labels, "Apply with catheter under aseptic conditions," suggested the introduction of the article into the uterus by means of a catheter, whereas the article, when introduced into the uterus, would be dangerous to health; and (2) in that the statements, "Stero-Uteroids * * * Directions: Apply with catheter under aseptic conditions. For administration by physician only," borne on the labels, were false and misleading since they represented and suggested that the article was a safe medicament for introduction into the uterus under aseptic conditions by a physician, whereas the article was not a safe medicament for introduction into the uterus under aseptic conditions, or any condition, by a physician or other person.

On April 3, 1944, the defendants having entered pleas of guilty, the court imposed a fine of \$100 on each of 2 counts, a total fine of \$200.

1303. Adulteration and misbranding of Rx 56 Special Prescription Compound for Alcoholism. U. S. v. Mrs. Ethel G. Jeffery (Mar-Dor Laboratories). Plea of guilty. Imposition of sentence suspended, and defendant placed on probation for 2 years, conditioned upon the discontinuance of the sale of medical articles. (F. D. C. No. 12552. Sample No. 8174-F.)

On September 11, 1944, the United States attorney for the District of Minnesota filed an information against Ethel G. Jeffery, trading as the Mar-Dor Laboratories, Minneapolis, Minn., alleging shipment of a quantity of the above-named product on or about August 21, 1943, from the State of Minnesota into the State of Wisconsin.

Analysis of a sample disclosed that the article was in the form of capsules, each of which contained 0.21 gram of potassium bromide, 6.4 milligrams of benzedrine sulfate, and thiamine chloride.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it purported and was represented to contain 0.4 gram of potassium bromide in each capsule, whereas it contained not more than 0.21 gram of potassium bromide in each capsule.

The article was alleged to be misbranded (1) because of false and misleading statements on its label and in the accompanying leaflet and circular entitled, "Instructions for Rx 56 Treatment for Alcoholism," and "Rx56' Special Compound An Aid to Drinkers," respectively, regarding its efficacy in the cure, mitigation, treatment, and prevention of alcoholism; (2) in that the statement on the label, "Potassium Bromide Grams 0.4 * * * Each Capsule," was false and misleading; and (3) in that the article, because of the presence of 6.4 milligrams of benzedrine sulfate, would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the aforesaid circular, i.e., "This treatment for the average patient using 1 to 3 capsules a day."

On October 14, 1944, the defendant having entered a plea of guilty, the court suspended imposition of sentence, and placed her on probation for a period of 2 years, conditioned that she refrain from engaging in the sale of medical articles of any kind.

1304. Misbranding of Lambert's Tablets and Lambert's Powders. U. S. v. Claude M. Stanley (Stanley Drug Co.). Plea of guilty. Fine, \$50 on first count; sentence suspended on second count, and defendant placed on 1 year's probation. (F. D. C. No. 11410. Sample Nos. 47507-F, 47508-F.)

On June 12, 1944, the United States attorney for the District of Minnesota filed an information against Claude M. Stanley, trading as the Stanley Drug Co., at Minneapolis, Minn., alleging shipment on or about July 23, 1943, from the State of Minnesota into the State of Iowa of a quantity of the above-named articles.

Analysis showed that the tablets each contained 2½ grains of aspirin, 1¼ grains of acetanilid, and 1¼ grains of salol, and that the powders each contained 5.74 grains of aspirin, 2.44 grains of acetanilid, and 2.81 grains of salol.

The articles were alleged to be misbranded (1) in that they would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in the labeling, (tablets) "Directions Take * * * 2 tablets with a glass of water. Repeat dose every 3 or 4 hours, preferably before eating and at bedtime," and (powders) "Directions Adult Dose—The contents of one powder, with a large glass of water, taken before meals, three times a day," since they contained approximately 1¼ grains of acetanilid per tablet, and approximately 2½ grains of acetanilid per powder, and their use, as prescribed, recommended, and suggested in the directions, would result in the administration of excessive amounts of acetanilid; (2) in that the labeling failed to bear warnings that frequent or continuous use might cause serious blood disturbances, anemia, collapse, or dependence on the article; and the labeling of the tablets failed to reveal that they should not be given to children; (3) in that the statements in the labeling, (tablets) "For relief of * * * discomfort in * * * muscular aches and pains, neuralgia, common head colds," and (powders) "For Relief Of Simple Colds, * * * Muscular Aches, Body Pains, Caused By Exposure," were false and misleading since the articles would not be efficacious for such purposes; and (4) in that the statements on the box containing the powders, "Acetylsalicylic Acid Grs. 5 * * * Phenyl Salicylate Grs. 2.5," were false and misleading since the article contained materially more than 5 grains of acetylsalicylic acid, and materially more than 2.5 grains of phenyl salicylate.

On December 1, 1944, the defendant having entered a plea of guilty, the court imposed a fine of \$50 on the first count of the information, suspended imposition of sentence on the second count, and placed the defendant on probation for the period of 1 year.