D. D. N. J., F. D. C. 1301-1350

Issued November 1945

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1301—1350

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*
WASHINGTON, D. C., *July 19, 1945.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1301. Misbranding of phenobarbital sodium ampuls and procaine hydrochloride ampuls. U. S. v. Loeser Laboratory, Inc., and Karl B. Rosen. Pleas of guilty. Corporate defendant fined $1,400; imposition of sentence suspended against individual defendant, who was placed on probation for 30 days. (F. D. C. No. 12556. Sample Nos. 50011-F, 50257-F, 51778-F, 51779-F, 65986-F, 65987-F, 77807-F.)

On November 6, 1944, the United States attorney for the Southern District of New York filed an information against the Loeser Laboratory, Inc., New York, N. Y., and Karl B. Rosen, secretary of the corporation, alleging shipment of a quantity of phenobarbital sodium ampuls from the State of New York into the State of New Jersey on or about December 2, 1943, and shipment of quantities of procaine hydrochloride ampuls from the State of New York into the States of New Jersey, Pennsylvania, and New Hampshire between the approximate dates of June 18 and December 13, 1943. The articles were labeled in part: "Phenobarbital Sodium [or "Procaine Hydrochloride"]

*For presence of a habit-forming narcotic without warning statement, see No. 1306; presence of an uncertified coal-tar color, No. 1345; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 1309, 1324, 1325; failure to bear an accurate statement of the quantity of the contents, Nos. 1306, 1309, 1324, 1326, 1336, 1337; omission of, or unsatisfactory, ingredients statements, Nos. 1307, 1309, 1314, 1326, 1338, 1341; inconspicuousness of required label information, Nos. 1328, 1334; deceptive packaging, No. 1337; cosmetics, subject to the drug provisions of the Act, Nos. 1335, 1337.

* * * 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.