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]

1151–1200

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., April 5, 1945.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1151. Adulteration and misbranding of Eli-606 Capsules and misbranding of Stero-Uteroids. U. S. v. Charles A. Ainsworth (Ainsworth Specialty Co.). Plea of guilty. Fine, $350. (F. D. C. No. 10542. Sample Nos. 3311-F, 37824-F.)

On September 17, 1943, the United States attorney for the Western District of Missouri filed an information against Charles A. Ainsworth, trading as the Ainsworth Specialty Co., Kansas City, Mo., alleging shipment from the State of Missouri into the State of Oklahoma, on or about January 21, 1943, of a quantity of Eli-606 Capsules, and into the State of Illinois from on or about July 24, 1941, to October 17, 1942, of quantities of Stero-Uteroids.

Analysis of the Eli-606 Capsules disclosed that the article contained per capsule 0.154 grain of sodium cacodylate, and not more than 0.89 grain of methenamine, 0.386 grain of acetanilid, 0.49 grain of calcium phosphate, and 0.476 grain of sodium phosphate.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain in each capsule ½ grain of sodium cacodylate, 2 grains of methenamine, and 1 grain each of acetanilid, calcium phosphate, and sodium phosphate, whereas it contained smaller amounts of those substances. It was alleged to be misbranded in that the statements on its label, "Formula: Soda Cacodylate ½ Gr. * * *

*For presence of a habit-forming narcotic without warning statement, see Nos. 1152, 1163; deceptive pack; aging, No. 1155; failure to bear accurate statement of quantity of contents, Nos. 1156, 1182, 1190, 1191, 1196; omission of, or unsatisfactory, ingredients statement, Nos. 1157, 1188, 1196; inconspicuousness of, or unsatisfactory, required label information, Nos. 1158, 1160; imitation of another drug, No. 1190; cosmetics, subject to the drug provisions of the Act, Nos. 1193, 1194.

Methenamine 2 Grs. * * * Acetanilide. Calc. Phosphate. Sodium Phosphate aa. 1 Gr. * * *," were false and misleading; and in that the statements "Formula * * * to make one 10 grain capsule," appearing on its label, and "FORMULA * * * for each 10 gr. capsule," appearing in the circular accompanying the article, were false and misleading since they represented and suggested that each of the capsules contained 10 grains of the article, whereas, each capsule contained a smaller amount. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious as an antiluetic, urinary antiseptic, alterative, blood cleanser, blood tonic, and as a substitute for or supplement to intravenous medication in luetic-syphilitic cases; and that it would be efficacious in the cure, mitigation, treatment, or prevention of gonorrhea, venereal discharges and infections, blood dyscrasias, malarial poisoning, anemias, lowered blood count, hepatic (liver) torpor, gallstones, and urinary infections, generally.

Analysis of the Stero-Uteroids disclosed that they consisted essentially of small proportions of zinc sulfate, plant material including an alkaloid-bearing drug, ichthammol, and a minute amount of iodine incorporated in lanolin.

The Stero-Uteroids were alleged to be misbranded in that the article would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in the labeling, since the name of the article, "Stero-Uteroids," the manner of packaging, i.e., collapsible metal tube with key, and the directions of a portion, "Apply with catheter under aseptic conditions," suggested the introduction of the article into the uterus, whereas the article, when introduced into the uterus, would be dangerous. It was alleged to be misbranded further in that the statements (portion), "Stero-Uteroids * * * to be used only by or on the prescription of a physician," and (remainder) "Stero-Uteroids * * * Directions: Apply with catheter under aseptic conditions. For administration by physician only," appearing in the labeling, were false and misleading since they represented and suggested that the article was a safe medicament for introduction into the uterus, whereas it was not a safe medicament for introduction into the uterus.

On October 11, 1943, the defendant entered a plea of guilty and the court imposed a fine of $50 on each of the 7 counts, a total fine of $350.

1152. Adulteration and misbranding of Trems. U. S. v. 19½ Dozen Packages and 130 Packages of Trems. Default decrees of condemnation and destruction. (F. D. C. Nos. 9559, 11654. Sample Nos. 712–F, 59514–F.)

On March 22, 1943, and January 18, 1944, the United States attorneys for the Northern District of Illinois and the Eastern District of Michigan filed libels against 19½ dozen packages and 130 packages of Trems at Detroit, Mich., and Chicago, Ill., respectively, alleging that the article had been shipped on or about February 10 and August 31, 1943, by Trems, Inc., St. Louis, Mo.; and charging that it was misbranded and that a portion was adulterated.

Examination disclosed that the article was in the form of tablets which contained phenobarbital, aspirin, and caffeine. One shipment contained 1 grain and the other contained 0.77 grain of phenobarbital per tablet.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, "Dosage: Sleeplessness—For adults, two tablets 20 minutes before retiring. * * * Other Symptoms—One to two tablets as required," since the article contained phenobarbital, a drug which cannot be administered with safety except under competent supervision, and the directions which appeared in the labeling did not provide for any limitation in the dosage, but implied that the article might be taken as frequently as desired with safety. It was alleged to be misbranded further in that it was for use by man and contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been by the Federal Security Administrator, after investigation, found to be, and by regulations designated as, habit-forming, and its labeling failed to bear the statement "Warning—May be habit forming," in juxtaposition with the name and quantity or proportion of the derivative of barbituric acid. In addition, in the case of the Chicago lot, its label failed to bear, as the regulations specify, the name and quantity or proportion of phenobarbital and the statement "Warning—May be habit forming" immediately following, without intervening written, printed, or graphic matter, the name by which the article was titled.