

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 anti-luetic, 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 gonorrhoea, 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.

The article in the Detroit lot was alleged to be misbranded further in that the statement, "Each Tablet Contains Phenobarbital 1 Gr.," appearing on its label, was false and misleading as applied to an article which did not contain, in each tablet, 1 grain of phenobarbital. It was alleged to be adulterated in that its strength differed from that which it was represented to possess.

On February 21 and May 19, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

1153. Adulteration and misbranding of Akerite Glycerin Alternate B-100 (glycerin substitute or alternate). U. S. v. Akerite Chemical Works, Inc. Plea of guilty. Fine, \$3,004 and costs. (F. D. C. No. 9679. Sample Nos. 6594-F, 2333-F, 23346-F.)

On October 25, 1943, the United States attorney for the Northern District of Illinois filed an information against the Akerite Chemical Works, Inc., Chicago, Ill., alleging shipment of quantities of the above-named product from the State of Illinois into the States of Missouri and Pennsylvania on or about September 9, 1942, and January 20 and February 4, 1943.

It was also alleged in the information that prior to the dates of the 1943 shipment the defendant represented the article as a nontoxic substitute for glycerin by causing to be prepared and distributed a circular entitled "Akerite Glycerin Substitute," which contained the following statements: "Akerite Glycerin Substitute is an aqueous solution derived from dextrin, starch and corn sugar by a special process. It is non-toxic"; and that prior to the date of the 1942 shipment the defendant represented the article as a nontoxic alternate for glycerin by means of a written communication, addressed by the defendant to the consignee, which contained the following statement: "Glycerin Alternate * * * Akerite Glycerin Alternative, an aqueous nontoxic liquid derived mainly from corn."

The article was alleged to be adulterated in that it was represented as a nontoxic substitute or nontoxic alternate for glycerin, which is a nonpoisonous substance, whereas the article consisted in large part of diethylene glycol, a poisonous chemical compound. It was alleged to be further adulterated in that a toxic substance, i. e., a substance containing diethylene glycol, had been substituted in whole or in part for the article.

A portion of the article (two shipments) was alleged to be misbranded because of false and misleading statements on the labels which represented and suggested that it was a substitute for glycerin, a nonpoisonous substance.

It was also alleged in the information with respect to the two shipments that the article was a new drug since it was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions suggested in its labeling, i. e., "Glycerin Substitute," and application filed pursuant to the law was not effective with respect to the article.

On December 30, 1943, the defendant having entered a plea of guilty, the court imposed a fine of \$1,000 on each of the 3 counts charging adulteration, and a fine of \$1 on each of the other counts, a total fine of \$3,004 plus costs.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1154. Misbranding of Sano. U. S. v. William J. Nassano (Sano Medicine Co.) Plea of guilty. Fine, \$250 and costs. (F. D. C. No. 10619. Sample No. 46330-F.)

On February 3, 1944, the United States attorney for the Northern District of Ohio filed an information against William J. Nassano, trading as the Sano Medicine Co., Cleveland, Ohio, alleging shipment of a quantity of Sano on or about February 7, 1943, from the State of Ohio into the State of Virginia.

Analysis disclosed that the article consisted of a brown liquid with sediment, containing water, alcohol, and plant extractives, including emodin-bearing drugs and a trace of unidentified alkaloids.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that the article was a diuretic and a tonic; that it would be efficacious as an internal medicine and aid in the relief of rheumatism; that it would assist in eliminating uric acids