611. Misbranding of Bron-Chu-Line Emulsion. U. S. v. 21 Bottles of Bron-Chu-Line Emulsion. Default decree of condemnation and destruction. (F. D. C. No. 5928. Sample No. 42975–E.)

In addition to failure to bear adequate warning statements, the labeling of this product contained false and misleading claims regarding its efficacy in the conditions indicated hereinafter.

On September 30, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against the above-named product at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about July 17, 1941, by the Johnstone Drug Sales Corporation from Rochester, N. Y.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of creosote, calcium, sodium and phosphorus compounds, benzyl alcohol, methyl salicylate, and gum acacia emulsified in a mineral oil.

It was alleged to be misbranded in that the statements in the labeling, "Bron-Chu-Line * * * Antispasmodic * * * of rare value in the treatment of irritated conditions of the respiratory passages * * * Beechwood Creosote possess values as an anti-pathogen, equal to if not superior to carbolic acid, and has long been considered of superior worth where any tubercular tendency is involved. * * * Methyl Salicylate acts as an eliminant of urea, uric acid and other acid waste matter whose excess presence is detrimental to recovery, such an excess of waste acid matter being a common presence where coughs, colds and catarrhal conditions are persistent; * * * Calcium and Sodium Hypophosphites are reconstructive tonics. In respiratory affections there is a constant waste of these vital body salts through expectoration. Such waste lowers body resistance and the presence of these Hypophosphites in the prescription is to afford resupply for body need. * * * We especially recommend Bron-Chu-Line Emulsion in such cases that the usual lozenge or home remedy has failed to relieve," were false and misleading since they indicated that it was of value in conditions involving the bronchi or lungs; whereas it was of no such value since it was essentially an expectorant and was not an antispasmodic, and it was not of real value in the treatment of irritated conditions of the respiratory passages; Beechwood Creosote was not present in sufficient quantity to be an anti-pathogen, and methyl salicylate was not present in the article in sufficient quantity to be an eliminant of urea, uric acid, and other acid waste matter when used as directed, and urea, uric acid, and other waste matter are not commonly present in excess where coughs, colds, and catarrhal conditions are persistent; calcium and sodium hypophosphites are not reconstructive tonics; there is not a constant waste through expectoration of calcium and sodium hypophosphites in respiratory affections; calcium and sodium hypophosphites are not vital body salts; and waste of calcium and sodium hypophosphites does not lower body resistance; and the product would not be efficacious in cases in which the usual lozenge or home remedy had failed to provide relief. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against use in those pathological conditions such as persistent cough or high fever where its use might be dangerous to health, or against unsafe duration of administration, since the duration of administration was not limited to 10 days, nor was the warning in such manner and form as is necessary for the protection of users.

On November 25, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

612. Misbranding of Ches-O-Kol. U. S. v. 199 Pounds of a Drug and 16 Dozen Packages of the same drug labeled "Ches-O-Kol." Default decree of condemnation and destruction. (F. D. C. No. 4896. Sample No. 37049–E.)

The drum in which this product was shipped failed to bear adequate directions for use and a statement of the common or usual name of the active ingredients. A portion had been repackaged in jars and cartons which bore on the labels false and misleading curative and therapeutic claims.

On June 24, 1941, the United States attorney for the Western District of South Carolina filed a libel against a drum containing 199 pounds and 16 dozen packages of Ches-O-Kol at Spartanburg, S. C., alleging that the article originally had been shipped on or about January 21, 1941, by the William A. Webster Co. from Memphis, Tenn., and that a portion (16 dozen packages) had been repackaged in 1½-ounce bottles and was in possession of the Ches-O-Kol Co., Spartanburg, S. C.; and charging that both lots were misbranded.

Analysis showed that the article consisted essentially of camphor, menthol, eucalyptol, and turpentine in a petrolatum base.

The article in the original drum was alleged to be misbranded in that its labeling did not bear adequate directions for use, since there were no directions for use on the drum; and in that it had been fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient. The repackaged product was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the treatment of chest colds, head colds, sore throat, croup due to colds, pneumonia, rheumatism, all skin diseases, dry, tickling coughs, sinus trouble, hay fever, flu, and that it would penetrate and relieve congestion, were false and misleading since it would not be efficacious for such purposes.

On August 7, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

613. Misbranding of Comfortt Tablets. U. S. v. 196 Boxes each containing 12 Comfortt Tablets. Default decree of condemnation and destruction. (F. D. C. No. 4895. Sample No. 65614–E.)

These tablets, which contained acetophenetidin, aspirin, and caffeine, originally were shipped in bulk, but subsequently were repackaged by the consignee. After such repackaging, the labeling in addition to failure to bear adequate directions for use and the required warning statements, also failed to declare the aspirin present by its common or usual name.

On June 10, 1941, the United States attorney for the District of Colorado filed a libel against the above-named product, alleging that on or about March 30, 1940, a consignment of a drug product labeled in part "Special Compressed Tablets R/2020 Eng. Comfortt" had been shipped from St. Louis, Mo., to College Laboratories, Inc., Denver, Colo., and that thereafter the latter firm had repackaged said product in boxes labeled in part "Comfortt Tablets"; and charging that as so repackaged it was misbranded as follows:

(1) In that it failed to bear adequate directions for use since those appearing on the box, namely, "Take one tablet and repeat in 30 minutes if needed, then one every 2 hours if needed. See your physician promptly if not relieved," did not limit dosage; (2) in that the labeling did not bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since it failed to warn that frequent or continued use might be dangerous, causing serious blood disturbances, and that not more than the recommended dose should be taken; and (3) in that the label did not bear the common or usual names of the active ingredients, since aspirin had been declared by its chemical name of acetylsalicylic acid and not by its common or usual name.

On August 2, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

614. Misbranding of Dye's Compound Tablets and Dye's Laxative Pellets. U. S. v. 8 Dozen Packages of Dye's Compound Tablets and 2 Dozen Packages of Dye's Laxative Pellets. Default decrees of condemnation and destruction. (F. D. C. Nos. 5083, 5084, 5636. Sample Nos. 7678–E, 7679–E.)

The labeling of the laxative pellets failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users. The labeling of both products bore false and misleading curative and therapeutic claims, and the containers were substantially larger than was necessary.

On July 8 and September 11, 1941, the United States attorney for the Southern District of California filed libels against the above-named drugs at Los Angeles, Calif., alleging that they had been shipped in interstate commerce on or about May 8 and 21 and June 10, 1941 by Dr. J. H. Dye Medical Co. from Buffalo, N. Y.; and charging that they were misbranded.

Analyses of samples showed that the compound tablets consisted of plant extractives, including valeric acid and alkaloid-containing plant drugs; and that the laxative pellets consisted essentially of aloin, podophyllum resin, and hydrastis.

The laxative pellets were alleged to be misbranded (1) in that the labeling did not bear adequate directions for use since the directions called for the administration of a laxative over an indefinite period of time; (2) in that the labeling did not bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe duration of administration in such manner and form as are necessary for the protection of users, since the labeling did not warn that frequent and continued