

that it had been shipped on or about November 7, 1941, by the Norwich Pharmacal Co. from Norwich, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that the tablets each contained acetanilid (1 grain), a coal-tar analgesic drug, podophyllin, aloin, and other drugs of plant origin including quinine, camphor, and cayenne pepper.

The article was alleged to be misbranded: (1) In that the labeling did not bear such adequate warnings against unsafe duration of administration as are necessary for the protection of users, since it failed to warn the consumer that frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug, and that it should be discontinued if skin rash appears. (2) In that statements in the labeling representing that it would affect the underlying cause of the common cold, prevent its full development, and shorten its duration were false and misleading, since its therapeutic efficacy was limited to that of an analgesic and laxative which might temporarily ameliorate some of the symptoms of the common cold, but not those of feverishness, tickling throat sensations, and running of the nose.

On April 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**668. Adulteration and misbranding of Pinee. U. S. v. 90 Bottles of Pinee. Default decree of condemnation and destruction. (F. D. C. No. 6549. Sample No. 59472-E.)**

In addition to containing smaller proportions of acetanilid and alcohol than those stated on the label, this product failed to bear on its label adequate directions for use and warning statements. The label also contained false and misleading therapeutic claims; and the statements of the active ingredients and quantity of contents and directions for use were in type so small as to be illegible.

On December 19, 1941, the United States attorney for the Eastern District of Virginia filed a libel against the above-named product at Emporia, Va., alleging that it had been shipped on or about October 1, 1941, by the Pinee Chemical Co. from Kinston, N. C.; and charging that it was adulterated and misbranded.

Analysis of a sample of the article showed that it consisted essentially of acetanilid (not more than 3.6 grains per fluid ounce), alcohol (not more than 10.9 percent), small amounts of menthol, camphor, laxative plant drugs, ammonia, ammonium chloride, licorice, and a trace of alkaloids.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, namely, "Acetanilid 6 grs to oz Maximum Alcohol 20 per cent."

It was alleged to be misbranded: (1) In that the labeling did not bear adequate directions for use since those appearing on the label provided for continuous administration and such directions were inadequate for a laxative since when taken in such manner it might create a dependence on laxatives (2) In that the labeling did not bear adequate warnings against use in those pathological conditions or by children 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 the labeling failed to warn that frequent or continued use might result in dependence on laxatives. (3) In that the following statements appearing in the labeling, together with the design of pine trees and pine cones on the bottle label, (carton) "Pinee For Colds," and (bottle label) "Pinee Colds \* \* \* Very effective In Treatment of Head & Chest Colds \* \* \* Contents Acetanilid 6 Grs to oz Maximum Alcohol 20 per cent," were false and misleading since the article contained no ingredient or combination of ingredients capable of preventing or curing either head or chest colds or of alleviating the common symptoms characteristic of colds, and it contained no materials derived from pine trees or pine cones, as implied by the designs on the label. (4) In that the required statements of the active ingredients, of the quantity of contents, and the directions for use did not appear on the label with such prominence or conspicuousness as to render them likely to be read or understood by the ordinary individual under customary conditions of purchase and use, since they appeared in type so small as to be illegible.

On February 18, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**669. Misbranding of Special Formula Tablets. U. S. v. 47,800 Special Formula Tablets, Plain. Default decree of condemnation and destruction. (F. D. C. No. 6301. Sample Nos. 87220-E, 87221-E.)**

This product consisted of tablets containing boric acid and an effervescent mixture of soda and citric acid. Its use might produce deleterious effects and its

label failed to bear adequate directions for use, adequate warnings, and the names of the active ingredients.

On November 28, 1941, the United States attorney for the Southern District of West Virginia filed a libel against the above-named product at Charleston, W. Va., alleging that the article had been shipped in interstate commerce on or about October 15, 1941, by the Arner Co., Inc., from Buffalo, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded in that its label failed to bear (1) adequate directions for use; (2) adequate warnings against use by children where its use might be dangerous to health, and against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users, since the labeling carried no warning that repeated daily administration would cause systemic deleterious effects and injurious gastro-intestinal disturbances; and (3) the common or usual name of each active ingredient.

On April 20, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**670. Misbranding of Special S. C. White Pills Rx2609. U. S. v. 96,200 Special S. C. White Pills Rx2609. Default decree of condemnation and destruction. (F. D. C. No. 6744. Sample No. 30492-E.)**

On January 21, 1942, the United States attorney for the Eastern District of Michigan filed a libel against the above-named product at Detroit, Mich., alleging that it had been shipped on or about November 22, 1941, by Charles H. Dietz, Inc., from St. Louis, Mo.; and charging that it was misbranded. The article was labeled in part: "Special S. C. White Pills Rx2609. Each pill contains—Aloes— $\frac{3}{4}$  gr. Ferrous Sulphate— $1\frac{1}{4}$  gr. Oil Pennyroyal— $\frac{1}{4}$  min."

It was alleged to be misbranded (1) in that the label did not bear adequate directions for use; and (2) in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health since the label failed to bear a warning that it should not be taken when nausea, vomiting, abdominal pains, or other symptoms of appendicitis are present; and against unsafe dosage or duration of administration since the labeling failed to bear a warning that frequent or continued use might result in dependence on a laxative.

On March 24, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**671. Misbranding of Sterile Solution Formula No. 3, Rx Formula No. 8, and S. G. M. a. (Oral). U. S. v. 8 Vials of Sterile Solution Formula No. 3, 12 Boxes of Rx Formula No. 8, and 4 Bottles of S. G. M. a. (Oral). Default decree of condemnation and destruction. (F. D. C. No. 3911. Sample Nos. 50191-E, 50195-E, 50196-E.)**

The labeling of the Sterile Solution Formula No. 3 and S. G. M. a (Oral) failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users and failed to bear the common or usual names of the active ingredients including the amount of strychnine in the former and of thyroid in the latter. The labeling of all three products failed to comply with certain other labeling requirements, as indicated hereinafter.

On February 4, 1941, the United States attorney for the Eastern District of Virginia filed a libel against the above-named products at Richmond, Va., alleging that they had been shipped in interstate commerce on or about December 31, 1940, by The Samaritan Treatment from Chicago, Ill.; and charging that they were misbranded.

Analysis of a sample of the Sterile Solution Formula No. 3 showed that it contained a solution of strychnine, emetine, ephedrine, pilocarpine, and sparteine. It was alleged to be misbranded (1) in that the label failed to bear adequate directions for use; (2) in that the label failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users; and (3) in that the label failed to bear the common or usual name of each of the active ingredients, including the amount of strychnine that it contained.

Analysis of a sample of Rx Formula No. 8 showed that the capsules each contained approximately 0.6 gram of a powder composed chiefly of iron and ammonium citrate. They were alleged to be misbranded in that they did not bear a label containing the name and place of business of the manufacturer, packer, or distributor; in that they did not bear a label containing a statement of the quantity of contents of the package; in that the label failed to bear the common