

1005. Misbranding of Pro-Nausea. U. S. v. 34 Bottles of Pro-Nausea. Decrees of condemnation and destruction. (F. D. C. No. 9553. Sample No. 35117-F.)

On March 29, 1943, the United States attorney for the Middle District of Alabama filed a libel against 34 bottles of Pro-Nausea at Phenix City, Ala., alleging that the article has been shipped in interstate commerce on or about January 28, 1943, from Griffin, Ga., by Dr. Thomas D. Thurmond; and charging that it was misbranded in violation of Sections 502 (a), 502 (e) (2), and 502 (j) of the Federal Food, Drug, and Cosmetic Act.

Examination showed that the article consisted essentially of sodium bromide, 110 grains per fluid ounce, and water.

The foregoing misbranding charges were based on the following recommendations made by the Federal Security Agency: Section 502 (j), that the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "Dose for Adult:—One table spoonful. Take one table spoonful of water after each dose. PRO-NAUSEA Relieves Vomiting During Pregnancy. Dose:—One table spoonful 30 minutes before meals. Take one table spoonful of water after each dose," since such directions provided for the taking of an excessive quantity of sodium bromide; Section 502 (a), that the following statements appearing on the label: "PRO-NAUSEA * * * Nonpoisonous Remedy for Sick Stomach Sick Headache Sea Sickness Nausea Following X-Ray Treatment * * * PRO-NAUSEA Relieves Vomiting During Pregnancy," were false and misleading since such statements represented and suggested that the article was a safe and effective treatment for the conditions described, whereas it was not a safe and effective treatment for such conditions, and was a dangerous drug; and Section 502 (e) (2), that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of sodium bromide contained therein.

On June 28, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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

1006. Action to enjoin and restrain interstate shipments of Mrs. Price's Specially Prepared Package of Boric Acid. U. S. v. Metta T. Price (Price Compound Co.) Permanent injunction granted. (Inj. No. 57.)

On June 21, 1943, the United States attorney for the District of Minnesota filed a complaint for the purpose of enjoining Metta T. Price, doing business as the Price Compound Co., Minneapolis, Minn., from the sale and distribution of chemical preservatives offered for use in home canning and food preservation, alleging, among other things:

That, since about the year 1937, the defendant had been engaged in the sale and distribution in interstate commerce of a product known as "Mrs. Price's Specially Prepared Package of Boric Acid," which upon examination was found to consist of 100 percent boric acid.

That, commencing on or about September 23, 1942, and again about the middle of May 1943, the product was the subject of numerous libel actions in various Federal judicial districts throughout the United States, and that the article so shipped was misbranded (1) in that the statements in the labeling which represented, suggested, and engendered the impression in the minds of the readers that the product, when used as directed in the canning of vegetables, fruits, pickles, and preserves, was safe and appropriate for such use, and would effect proper sterilization, conservation, and preservation of home-canned foods, were false and misleading, since it was potentially dangerous to the health of the consumer and would not insure proper sterilization, conservation, and preservation of home-canned foods; (2) the statements in the labeling admonishing the home canner to sterilize jars, and particularly the rubber rings, by boiling for 15 to 20 minutes were misleading, since these directions for sterilization are inadequate where heat-resistant, spore-forming bacteria are present; (3) in that the statement in the labeling, "Wash thoroughly as the most dangerous and the most difficult bacteria to destroy are in the soil," was misleading, since it represented and suggested that the thorough washing of vegetables would eliminate the most dangerous and difficult bacteria to destroy, whereas such washing would not insure that effect; (4) in that the statements in the labeling, "If the foregoing directions are followed and you have used good, fresh vegetables or fruits and the amount of compound directed, you will have no trouble in securing the best

*See also Nos. 1002, 1003.

results. You may ask why we are so particular to have the cans perfectly tight. The reason is that we wish you to do all you can mechanically to keep the goods, and then by the use of the compound, get a perfect result that neither one alone would secure," were false and misleading in that they represented and suggested that the use of the article according to directions would assure the perfect and best results in home canning, whereas the perfect and best results cannot be obtained by such use, since heat-resistant, spore-forming bacteria, capable of producing spoilage and toxins dangerous to health, would not be destroyed; and, (5) in that its labeling failed to bear adequate directions for use.

On June 28, 1943, the court entered its findings of fact and conclusions of law and order for permanent injunction, and on the same date judgment was entered enjoining the defendant, her employees, agents, distributors, attorneys, assigns, and any and all persons acting in concert with her, from introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce, of Mrs. Price's Specially Prepared Package of Boric Acid, or any similar article containing boric acid for any purpose in violation of the Federal Food, Drug and Cosmetic Act.

The product was also alleged to be misbranded under the provisions of the law applicable to foods, reported in food notices of judgment No. 5759, in which also appear the court's findings of fact and conclusions of law with respect to the product and two other products, Mrs. Price's Compound and Price's No-Ice.

1007. Misbranding of Chu-man-ie's Regular "Triple XXX" Herb and Iron Mensal Medicine. U. S. v. Charles Roehm (Chumanie Medicine Co.). Plea of not guilty. Tried to a jury. Verdict of guilty. Sentence of 6 months in jail suspended and defendant placed on probation for 1 year. (F. D. C. No. 7723. Sample No. 59725-E.)

On December 10, 1942, the United States attorney for the Eastern District of Michigan filed an information against Charles Roehm, trading as the Chumanie Medicine Co. at New Richmond, Ohio, and Detroit, Mich., alleging shipment on or about January 12, 1942, from the State of Michigan into the State of Maryland of a quantity of the above-named product.

Analysis of the article showed that it was in the form of tablets which contained ferrous sulfate and plant material, including aloe.

The article was alleged to be misbranded in that the statements in its labeling which represented and suggested that it would be efficacious as a mensal medicine, and would be efficacious in the treatment of amenorrhea (suppressed menstruation), oligomenorrhea (scanty or infrequent menstruation), and dysmenorrhea (difficult or painful menstruation), were false and misleading since the article would not be so efficacious. It was alleged to be misbranded further in that its labeling did not bear adequate directions for use, since it was a laxative and should not be used continuously, and the labeling failed to warn against continuous use of the article.

On December 7, 1943, the case came on for trial, and at its conclusion on December 9, 1943, the jury returned a verdict of guilty. The court imposed a sentence of 6 months in jail, but suspended the sentence and placed the defendant on probation for 1 year, specifying as a part of the probation that he was not to prepare or market the above-named product until he had submitted an acceptable label to the Food and Drug Administration.

1008. Misbranding of Dye's Compound Tablets and Dye's Laxative Pellets. U. S. v. Clara A. Skey (Dr. J. H. Dye Medical Co.). Plea of nolo contendere. Fine, \$150. (F. D. C. No. 6456. Sample Nos. 7673-E, 7674-E, 11173-E, 11174-E.)

On May 25, 1942, the United States attorney for the Western District of New York filed an information against Clara A. Skey, trading as the Dr. J. H. Dye Medical Co., Buffalo, N. Y., alleging shipment on or about January 17, and March 12 and 31, 1941, from the State of New York into the States of California and Texas of quantities of the above-named products which were misbranded.

Analyses showed that Dye's Compound Tablets consisted essentially of extracts of plant drugs including black haw and an alkaloid-bearing drug, and that Dye's Laxative Pellets consisted essentially of extracts of plant drugs including aoin, podophyllin, and Hydrastis.

The Dye's Compound Tablets were alleged to be misbranded in that the statements appearing in their labeling which represented and suggested that they would be efficacious in reducing the distressing symptoms of functional dysmenorrhea; that they would help build up physical resistance and tend to reduce minor nervous conditions due to functional painful menstruation; that they would be efficacious to increase the appetite and resistance; that they would be efficacious in