

1058. Misbranding of Davis Formula No. 7895 and standardized solution of vitamin A, and Anti-Ur-Acid and vitamin B₁ tablets. U. S. v. Edward R. Davis (E. R. Davis Prescription Co.). Plea of guilty. Fines, \$500 on count 1 and \$1 each on counts 2 and 3, plus costs. (F. D. C. No. 7742. Sample Nos. 23097-E, 93233-E, 95346-E.)

On July 30, 1943, the United States attorney for the Western District of Washington filed an information against Edward R. Davis, trading as the E. R. Davis Prescription Co., at Bellingham, Wash., alleging shipment from the State of Washington into the State of California, on or about December 17, 1941, and June 23, 1942, of a number of cartons, each containing a bottle of Davis Formula No. 7895 and a bottle of Standardized Solution of Vitamin A; and into the State of Oregon, on or about May 14, 1942, of a carton containing a box of Anti-Ur-Acid powder and a box of vitamin B₁ tablets.

Analysis showed that the Davis Formula No. 7895 consisted essentially of potassium iodide, an extract of a plant drug such as Lobelia, a small proportion of chloroform, sugar, alcohol, and water; and that the solution of vitamin A contained 32,500 U. S. P. units of vitamin A per gram.

The formula and the solution of vitamin A were alleged to be misbranded in that the statements in their labeling which represented and suggested that, when used as directed, with the diet suggested, they would be an adequate treatment for asthma, including bronchial and spasmodic asthma, were false and misleading since they would not be an adequate treatment for such conditions.

Analysis showed that the Anti-Ur-Acid was a powder consisting essentially of magnesium sulfate, potassium bitartrate, and sodium bicarbonate; and that the vitamin B₁ tablets contained between 0.90 mg. and 0.95 mg. of the vitamin per tablet.

The powder and the vitamin B₁ tablets were alleged to be misbranded in that the name "Anti-Ur-Acid" was misleading, since the name suggested and created the impression in the mind of the reader that the articles would neutralize and correct excess uric acid, whereas they would not neutralize or correct excess uric acid. They were alleged to be misbranded further in that the name "Anti-Ur-Acid," and the statements in the labeling which represented and suggested that rheumatic, neuritic, and arthritic pains, gout, dropsy, and similar disease conditions, suggested by the abbreviation "etc.," were caused by excess uric acid and that the articles would be efficacious in the treatment of those conditions, were false and misleading since those disease conditions are not caused by excess uric acid, and the articles would not be efficacious for the purposes claimed. The articles were alleged to be misbranded further in that the labeling failed to bear adequate directions for use, since the statement "Take about ½ hour before breakfast" created the impression that the powder should be taken every morning, whereas the powder was a laxative and should not be taken continuously.

On November 20, 1943, the defendant having entered a plea of guilty, the court imposed fines of \$500 on count 1 and \$1 each on counts 2 and 3, plus costs, a total fine of \$543.60.

1059. Misbranding of Mrs. Price's Specially Prepared Package of Boric Acid. U. S. v. 53 Packages of Mrs. Price's Specially Prepared Package of Boric Acid (and 5 other seizure actions against the same product). Default decrees of condemnation. Portion of the product ordered delivered to a local public institution; remainder ordered destroyed. (F. D. C. Nos. 9984, 9990 to 9993, incl., 10043. Sample Nos. 22645-F, 22647-F, 22773-F, 22775-F, 23281-F, 23282-F, 23284-F, 32514-F.)

Examination showed that this product consisted of boric acid meeting the requirements of the United States Pharmacopoeia.

Between May 20 and June 7, 1943, the United States attorneys for the Eastern and Middle Districts of Pennsylvania and the Northern District of Ohio filed libels against 53 packages at Wilkes-Barre, Pa., 186 packages at Philadelphia, Pa., 238 packages at Lancaster, Pa., 248 packages at Harrisburg, Pa., 115 packages at Northumberland, Pa., and 5 packages at Cleveland, Ohio, each package containing 12 envelopes of boric acid and 3 pamphlets entitled "Mrs. Price's Complete Directions For Canning Vegetables and Fruits Pickling, etc. * * * ." It was alleged that the article had been shipped within the period from on or about March 15 to April 21, 1943, from Minneapolis, Minn., by the Price Compound Company; and charged that it was misbranded.

The article was alleged to be misbranded (1) in that the statements in its labeling which represented and suggested that boric acid, when used as directed in the canning of vegetables, fruits, and pickles, might safely be used for those purposes, and would effect proper sterilization and destroy bacterial spores capable of causing spoilage, thereby preventing a substantial amount of waste

in home-canned products, were misleading, since such use would be potentially dangerous to the health of the consumer, would not insure proper sterilization, and would not destroy resistant bacterial spores capable of causing spoilage, and thus would not insure the prevention of a substantial amount of waste in home-canned products; (2) in that the statements in its labeling whereby the home canner was admonished to sterilize jars, and particularly rubber rings, by boiling for 15 or 20 minutes were misleading, since the directions for sterilizing were inadequate for the reason that sterilization of jars and rubber rings cannot always be accomplished by boiling for 15 or 20 minutes because of the heat resistance of spore-forming bacteria; (3) in that the statement in its labeling " * * * Wash thoroughly, as the most dangerous and the most difficult bacteria to destroy are in the soil," was misleading since it suggested and represented that the thorough washing of vegetables would eliminate the most dangerous and difficult bacteria to destroy, the common habitat of which is in soil, whereas thorough washing of vegetables will not insure such effects; and (4) in that the statements in its labeling, "Mrs. Price's Specially Prepared Package of Boric Acid Manufactured for, Prepared and Distributed by The Price Compound Company * * * Minneapolis, Minn. * * * It is not claimed that the contents of this package contains anything of food value," were misleading because they failed to reveal the consequences which might result from the use of the article under the conditions prescribed in the labeling, since the processing recommended would not insure proper sterilization and might thereby result in danger to health; and the label further failed to reveal that the amount of boric acid which might be ingested when used as prescribed was such as might render the product deleterious to health. The article was alleged to be misbranded further in that it was a drug and its labeling failed to bear adequate directions for use.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods, No. 5760.

Between June 26 and August 9, 1943, no claimant having appeared, judgments of condemnation were entered and it was ordered that the lots at Philadelphia and Lancaster be delivered for the use of some local public institution, and that the other lots be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1060. Adulteration and misbranding of ephedrine sulfate. U. S. v. Reuben Seltzer (Success Chemical Co.). Plea of guilty. Fine, \$750. (F. D. C. No. 9618. Sample No. 19062-F.)

Analysis of a sample of this product showed that it contained not more than 2.24 grams (2.24 percent) of ephedrine sulfate per 100 cc.

On May 18, 1943, the United States attorney for the Eastern District of New York filed an information against Reuben Seltzer, trading as the Success Chemical Co., Brooklyn, N. Y., alleging shipment on or about July 23, 1942, of a quantity of the above-named article from the State of New York into the State of New Jersey.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which, "Solution of Ephedrine Sulfate," is recognized in the National Formulary, an official compendium, but its strength differed from and its quality fell below the standard set forth in that compendium since it contained less than 2.8 grams of ephedrine sulphate in each 100 cc., whereas the Formulary provides that "Solution of Ephedrine Sulfate contains in each 100 cc., not less than 2.8 Gm. * * * of Ephedrine Sulfate"; and its difference in strength and quality from the standard set forth therein was not plainly stated on the label.

It was alleged to be misbranded in that the statement "Ephedrine Sulfate N. F. VI A Solution of 3% Ephedrine Sulfate," borne on its label, was false and misleading.

On June 17, 1943, the defendant having entered a plea of guilty, the court imposed a fine of \$250 on count 1, and \$500 on count 2, a total of \$750.

*See also Nos. 1054-1056.