856. Adulteration and misbranding of cascara compound tablets and Pentabisarsen ampuls. U. S. v. Max Gold and Irving Levine (Gold Leaf Pharmacal Co.). Plea of guilty. Fine, $500 on counts 2 and 4. Sentence suspended and defendants placed on probation for 1 year on counts 1 and 3. (F. D. C. No. 6466. Sample Nos. 69921-E, 69925-E.)

Both products were below their own standard. In addition, the cascara compound tablets did not bear adequate directions for use or warning statements.

On October 2, 1942, the United States attorney for the Southern District of New York filed an information against Max Gold and Irving Levine, trading as the Gold Leaf Pharmacal Co., New Rochelle, N. Y., alleging shipments of cascara compound tablets and of Pentabisarsen ampuls on or about May 9 to 12, 1941, from the State of New York into the State of Connecticut.

Analysis of a sample of the cascara compound tablets showed that they contained no strychnine sulfate, but did contain alkaloids of belladonna, aloin, podophyllin, and extracts of plant drugs, including ginger, and a laxative drug.

The article was alleged to be misbranded in that the statements on the label represented that each tablet contained 1/60 grain of strychnine sulfate, whereas it did not contain any strychnine sulfate. It was further misbranded in that the extract of belladonna, a constituent of the drug, contained the alkaloids atropine, hyoscine, and hyoscyamine, and the label failed to bear the name and quantity or proportion of those alkaloids. The article was also misbranded in that the labeling failed to bear adequate warnings against use by children and by persons in those pathological conditions wherein use of the drug may be dangerous to health; against unsafe dosage, or methods or duration of administration, or application in such manner and form as are necessary for the protection of users; and in that it did not bear warnings that the preparation should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use may result in dependence on laxatives.

The article was alleged to be adulterated in that its strength differed from and its purity and quality fell below that which it purported and was represented to possess, since it was represented to contain strychnine sulfate, but contained no strychnine sulfate.

Analysis of a sample of Pentabisarsen ampuls showed that the solution contained 1.28 percent of bismuth and 0.311 percent of arsenic.

It was alleged to be misbranded in that the statements appearing on the label representing the drug to contain 2 percent solution of sodium bismuth pentavalent, and organic ester of arsonic acid containing approximately 36 percent bismuth and 13 percent arsenic, were false and misleading as the quantities of said elements, based upon the standard so declared, were thus represented to be not more than 0.72 percent of bismuth and not more than 0.26 percent of arsenic, whereas the drug contained more bismuth and arsenic than declared.

The Pentabisarsen ampuls were also alleged to be adulterated in that their strength differed from and their purity and quality fell below that which they were represented and purported to possess.

On October 14, 1942, the defendants entered a plea of guilty and were fined $250 on counts 2 and 4 of the information, a total fine of $500. Imposition of sentence was suspended on counts 1 and 3, and each of the defendants was placed on probation for a period of 1 year.

857. Misbranding of Mrs. Price's special prepared boric acid. U. S. v. 92 Packages of Mrs. Price's Special Prepared Boric Acid. Default decree of condemnation and destruction. (F. D. C. No. 8974. Sample No. 22616-F.)

On December 11, 1942, the United States attorney for the Middle District of Pennsylvania filed a libel against the above-named product at Harrisburg, Pa., alleging that the article had been shipped in interstate commerce on or about September 16, 1942, by Mrs. W. T. Price under the designation Price Compound Co., from Minneapolis, Minn.; and charging that it was misbranded in that it was sold under a name recognized in the United States Pharmacopoeia, and purported to be and was represented as an antiseptic, and its labeling failed to bear adequate directions for use.

The article was also alleged to be misbranded under the provisions of the act applicable to foods, reported in F. N. J. No. 4489.

On February 12, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.