

1210. Adulteration and misbranding of solution of citrate of magnesia. U. S. v. Mordecai Seidman (M. Seidman). Plea of guilty. Fine, \$70 and costs. (F. D. C. No. 11390. Sample Nos. 64840-E, 21020-F, 34213-F, 37688-F.)

On April 14, 1944, the United States attorney for the Western District of Pennsylvania filed an information against Mordecai Seidman, an individual trading as M. Seidman, Pittsburgh, Pa., alleging shipment between the approximate dates of November 25, 1941, and June 22, 1943, from the State of Pennsylvania into the States of Ohio and Michigan of quantities of the above-named product. The article was labeled in part: (Bottles) "Effervescing Solution of Citrate of Magnesia. * * * Distributed by Superior Distributing Co. Pittsburgh, Pa."

Examination disclosed that the article contained approximately one-half as much syrup and, in the case of certain portions, two-thirds as much magnesium citrate, as provided by the United States Pharmacopoeia; and that various portions also contained sulfate in excess of the amount permitted by the Pharmacopoeia, and were not packaged in the manner prescribed therein.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the standard set forth therein, and its difference in strength and quality from the standard was not stated plainly, or at all, on its labels.

Various portions of the article were alleged to be misbranded (1) in that the statement on its label, "Solution of Citrate of Magnesia Made of pure citric acid and carbonate of magnesia according to the U. S. Pharmacopoeia * * * U. S. P.," was false and misleading; (2) in that it was not packaged as prescribed in the Pharmacopoeia, since that compendium provides: "Dispense Solution of Magnesium Citrate in bottles containing not less than 340 cc. and not more than 360 cc., or in bottles containing not less than 195 cc. and not more than 205 cc.," whereas the article was contained in bottles containing less than 340 cc. and more than 205 cc.; (3) in that the statement "11 Ozs.," borne on the bottle labels, was false and misleading since a number of the bottles contained less than 11 ounces of the article; and (4) in that a number of the bottles failed to bear a label containing an accurate statement of the quantity of the contents.

On May 5, 1944, the defendant having entered a plea of guilty, the court imposed a fine of \$10 on each of 7 counts, a total fine of \$70 and costs.

1211. Adulteration and misbranding of zinc oxide ointment, ammoniated mercury ointment, and carbolic ointment. U. S. v. The Trade Laboratories, Inc. Plea of guilty. Fine, \$200. (F. D. C. No. 11364. Sample Nos. 38279-F, 38602-F, 45450-F.)

On March 23, 1944, the United States attorney for the District of New Jersey filed an information against the Trade Laboratories, Inc., Newark, N. J., alleging shipment of quantities of the above-named products on or about February 13, April 7, and May 17, 1943, from the State of New Jersey into the States of Illinois and New York.

The zinc oxide ointment was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth therein since the compendium provides that zinc oxide ointment shall contain not less than 18.5 percent and not more than 21.5 percent of zinc oxide, whereas portions of the article contained zinc oxide in amounts varying from 12.84 percent to 17.98 percent, and a portion of the article contained not less than 22.65 percent of zinc oxide, and its difference in strength from the standard was not plainly stated on its label. The article was alleged to be misbranded in that the statement "Zinc Oxide Ointment U. S. P.," appearing on its label, was false and misleading.

The ammoniated mercury ointment was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, but its strength differed from the standard set forth therein since the compendium provides that ammoniated mercury ointment shall contain an amount of ammoniated mercury corresponding to not more than 4.5 percent of Hg. (mercury), whereas the article contained ammoniated mercury corresponding to amounts of mercury varying from 8.32 percent to 8.39 percent, and its difference in strength from the standard was not plainly stated on its label. The article was alleged to be misbranded in that the statement "Ammoniated Mercury Ointment * * * U. S. P.," borne on its labels, was false and misleading.

The carbolic ointment was alleged to be adulterated in that it purported to be and was represented as a drug the name of which, "Phenol Ointment" or "Ointment of Carbolic Acid," is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from or its quality fell below the standard set forth therein since the compendium provides that phenol ointment or ointment of carbolic acid shall contain not less than 1.8 percent of carbolic acid, whereas the article contained carbolic acid in amounts varying from 1.56 percent to 1.69 percent, and its difference in strength and quality from the standard was not plainly stated on its label. It was alleged to be misbranded in that the statements "Carbolic Ointment U. S. P.," and "Net Wgt. 1 Oz.," borne on its labels, were false and misleading since the article did not conform with the requirements of the Pharmacopoeia, and its containers did not contain 1 ounce net weight of the article but contained a smaller amount.

On June 26, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$200 on each of 6 counts. Payment of the fine on 5 of the counts was suspended.

1212. Adulteration of digitalis tablets and tincture of digitalis. U. S. v. Direct Sales Co., Inc. Plea of guilty. Fine, \$300. (F. D. C. No. 11336. Sample Nos. 21817-F, 21818-F.)

On January 24, 1944, the United States attorney for the Western District of New York filed an information against the Direct Sales Co., Inc., Buffalo, N. Y., alleging shipment of a quantity of the above-named products on or about January 19, 1943, from the State of New York into the State of Pennsylvania.

The digitalis tablets were alleged to be adulterated in that each tablet purported and was represented to possess a potency equivalent to not more than 0.62 digitalis unit, as defined in the United States Pharmacopoeia, whereas each tablet possessed a potency equivalent to not less than 1.35 digitalis units.

The tincture of digitalis was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard since 1 cc. of the article possessed a potency equivalent to not less than 1.86 U. S. P. digitalis units, which is 86 percent in excess of the potency of the official product, and its difference in strength was not plainly stated on its label.

On February 14, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$150 on each of 2 counts, a total fine of \$300.

1213. Adulteration of Bevitin (thiamine hydrochloride). U. S. v. 3,000 Ampuls and 12,000 Ampuls of Bevitin Brand of Thiamine Hydrochloride. Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 11289, 11290. Sample Nos. 29634-F, 29635-F.)

On December 9 and 20, 1943, the United States attorneys for the Eastern District of Missouri and the Southern District of Georgia filed libels against 3,000 ampuls of the above-named product at St. Louis, Mo., and 12,000 ampuls of the same product at Savannah, Ga., alleging that the article had been shipped on or about November 3, 1943, from Brooklyn, N. Y., by the Pro-Medico Laboratories, Inc.; and charging that it was adulterated.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, i. e., "Intravenous—Intramuscular," since it was not suitable for parenteral use because of contamination with undissolved material.

On February 24 and March 4, 1944, the Pro-Medico Laboratories, Inc., having appeared as claimant for the Georgia lot and having admitted the allegations of the libel, and no claimant having appeared for the Missouri lot, judgments of condemnation were entered and the Georgia lot was ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration, and the Missouri lot was ordered destroyed.

1214. Adulteration of suprarenalin solution. U. S. v. 432 Vials of Suprarenalin Solution. Default decree of condemnation and destruction. (F. D. C. No. 11519. Sample No. 65902-F.)

On January 3, 1944, the United States attorney for the Southern District of New York filed a libel against 432 vials of suprarenalin solution at New York, N. Y., alleging that the article had been shipped on or about November 12 and 26, 1943, by the Armour Laboratories, Chicago, Ill.; and charging that it was adulterated. The article was labeled in part: "Suprarenalin Solution 1 : 1,000 A brand of solution of epinephrine hydrochloride U. S. P. Sterile—For Hypodermatic Use."