

U. S. P.," and "Contains not less than 7% \* \* \* of Magnesium Hydroxide," were false and misleading since the article did not comply with the specifications of the United States Pharmacopoeia.

On August 24, 1942, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$40.

**816. Adulteration of ampuls of strontium bromide, triple distilled water, iron and arsenic, sodium iodide, Lactosan, and Solution Sal-Ar-Sodide. U. S. v. Cornelius L. Johnson (Haarlem Research Laboratories). Plea of guilty. Total fine, \$325. (F. D. C. No. 5557. Sample Nos. 24371-E, 24373-E to 24376-E, incl., 24385-E, 24391-E, 28036-E, 34842-E.)**

On August 5, 1942, the United States attorney for the Southern District of New York filed an information against Cornelius L. Johnson, trading as the Haarlem Research Laboratories at New York, N. Y., alleging shipment within the period from on or about the month of February, to on or about October 7, 1940, from the State of New York into the States of Pennsylvania, Maryland, and New Jersey of quantities of ampuls of the above-named drugs which were adulterated.

The strontium bromide was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since it purported and was represented to contain 15½ grains of strontium bromide in each 10 cc., whereas it contained not more than 12.59 grains of strontium bromide per 10 cc.

The triple distilled water 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 National Formulary, and its quality or purity fell below the standard set forth in such compendium since its contained sulfates and chlorides, ingredients which are not found in the official product and contained oxidizable substances in excess of the amounts permitted by the Formulary and the residue from 100 cc. was greater than the maximum permitted, 0.002 gram, and its difference from such standard was not plainly stated on its label.

The 2 shipments of iron and arsenic were alleged to be adulterated in that their strength differed from that which they purported and were represented to possess since the article in one shipment purported and was represented to contain in each 5 cc., 7.75 milligrams of iron and 32 milligrams of arsenic, whereas it contained in 5 cc. not less than 10.7 milligrams of iron and not less than 97.9 milligrams of arsenic; and the article in the other shipment was represented to contain in each 10 cc., 15.5 milligrams of iron and 64 milligrams of arsenic, whereas it contained in each 10 cc., not less than 24 milligrams of iron and not less than 190 milligrams of arsenic.

The sodium iodide 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 National Formulary, and its quality and purity fell below the standard set forth therein since it was not a clear aqueous solution but contained flocculent precipitate and its difference from such standard was not plainly stated on its label.

The Lactosan was alleged to be adulterated in that its strength differed from, and its quality fell below that which it purported and was represented to possess, as it was represented to contain in each 2 cc., ¾ grain of casein and 9/10 grain of sodium phosphate, whereas it contained in each 2 cc., not more than 0.304 (¾/10) grain of casein, and not more than 0.370 (less than ¾) grain of sodium phosphate.

The Solution Sal-Ar-Sodide was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and represented to possess since it purported and represented to contain in each 20 cc., 31 grains of sodium salicylate and 31 grains of sodium iodide, whereas it contained in each 20 cc., not more than 26.2 grains of sodium salicylate and not more than 27.4 grains of sodium iodide.

On September 10, 1942, the defendant having entered a plea of guilty, the court imposed a fine of \$100 on each of the second and third counts of the information, which involved the ampuls of triple distilled water and the 5 cc. ampuls of iron and arsenic, and imposed a fine of \$25 on each of the remaining five counts, a total of \$325.

**817. Adulteration and misbranding of digitalis leaves capsules. U. S. v. Philadelphia Capsule Co., Inc., and Joseph McManus. Pleas of nolo contendere. Defendants found guilty. Fines, \$250. (F. D. C. No. 7285. Sample No. 54329-E.)**

On August 19, 1942, the United States attorney for the Eastern District of Pennsylvania filed an information against the Philadelphia Capsule Co., Inc.,

Philadelphia, Pa., and Joseph McManus, alleging shipment on or about September 9, 1941, from the State of Pennsylvania into the State of New Jersey of a quantity of digitalis leaves capsules.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain 1 grain of digitalis leaves per capsule but it contained not more than 0.4 grain. It was alleged to be misbranded in that the label statement, "Capsules Digitalis Leaves Approximates 1 Gr.," was false and misleading.

On September 16, 1942, the defendants having entered please of nolo contendere, the court found them guilty and imposed a fine of \$125 against each defendant.

**818. Adulteration and misbranding of Estrovin. U. S. v. 950 ampuls of Estrovin. Default decree of condemnation and destruction. (F. D. C. No. 7634. Sample Nos. 7697-E, 7698-E.)**

The potency of this product was not greater than 1,100 international units of estrogenic ovarian follicular hormones per cubic centimeter, whereas it was represented to possess a potency of 5,000 such units per cubic centimeter.

On June 10, 1942, the United States attorney for the Southern District of California filed a libel against 950 ampuls of Estrovin at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about January 28, 1942, by the Adson-Intrasol Laboratories, Inc., from New York, N. Y.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, namely, 5,000 international units of estrogenic ovarian follicular hormones in each cubic centimeter.

It was alleged to be misbranded in that the following statements in the labeling: (Box containing 25 ampuls) "Estrovin in Oil \* \* \* 1 c. c. contains therapeutic activity of 5,000 i.u. of estrogenic ovarian follicular hormones," (individual ampul) "Estroin in Oil 1 c. c. 5,000 I.U." were false and misleading, since 1 cubic centimeter of the article did not contain the therapeutic activity of 5,000 international units of estrogenic ovarian follicular hormones.

On August 7, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**819. Adulteration of wheat germ. U. S. v. 161 Cases and 45 Cases of Wheat Germ. Default decree of condemnation and destruction. (F. D. C. No. 8399. Sample No. 16874-F.)**

On September 24, 1942, the United States attorney for the Southern District of New York filed a libel against 161 cases, each containing 12 ½-pound cans, and 45 cases, each containing 12 1-pound cans, of wheat germ at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about August 28, 1942, by the Battle Creek Food Co. from Battle Creek, Mich. The article was labeled in part: "Battle Creek Wheat Germ."

Examination of samples of the article showed that it contained less than 300 U. S. P. units of vitamin B<sub>1</sub> per ounce.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented on its label as possessing, 500 U. S. P. units of vitamin B<sub>1</sub> per ounce.

It was alleged to be misbranded (1) in that the statements on the label, "One ounce (approx. ½ cup) of Battle Creek Wheat Germ supplies 500 U. S. P. units of vitamin B<sub>1</sub> (Thiamin), (1½ times the minimum daily requirement for an adult)," was false and misleading since it contained less than 500 U. S. P. units of vitamin B<sub>1</sub> per ounce; and (2) in that the statements, "Wheat Germ fills a much-needed place in the modern diet which is apt to be deficient in Thiamin (vitamin B<sub>1</sub>) and Riboflavin (vitamin G). Vitamin B<sub>1</sub> tends to make steady nerves, improves appetite, aids digestion and combats constipation. Vitamin G promotes good nutrition; both vitamins help to build vital resistance. Battle Creek Wheat Germ presents a \* \* \* economical source of these important vitamins. One ounce (approx. ½ cup) of Battle Creek Wheat Germ supplies 500 U. S. P. units of vitamin B<sub>1</sub> (Thiamin), (1½ times the minimum daily requirement for an adult)," were misleading since they represented and suggested that adequate amounts of vitamin B<sub>1</sub> and riboflavin are not supplied by the ordinary diet and that the use of the article would promote steady nerves, improve the appetite, aid digestion, combat constipation, promote good nutrition, and build vital resistance, whereas vitamin B<sub>1</sub> and riboflavin are present in a wide variety of ordinary foods and are present in many ordinary diets in adequate amounts, and the use of the article would not correct or promote the conditions mentioned.