

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. ⅓ 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. ⅓ 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.

The article was also charged to be misbranded under the provisions of the law applicable to foods as reported in F. N. J. No. 4488.

On October 10, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**820. Adulteration and misbranding of nicotinic acid amide. U. S. v. 57 Bottles and 314 Bottles of Nicotinic Acid Amide. Default decrees of condemnation. Product ordered relabeled and delivered to State hospitals. (F. D. C. No. 8069, 8099. Sample Nos. 28408-F, 29121-F, 29131-F.)**

On August 10 and 12, 1942, the United States attorneys for the Northern and Southern District of Georgia filed libels against 57 bottles and 314 bottles of nicotinic acid amide at Atlanta and Savannah, Ga., alleging that the article had been shipped in interstate commerce on or about July 1 and 24, 1942, by Schieffelin & Co. from New York, N. Y. The article was labeled in part: "Nicotinic Acid Amide."

The article was alleged to be adulterated in that nicotinic acid had been substituted in whole or in part for nicotinic acid amide.

It was alleged to be misbranded in that the declaration on the label "Nicotinic Acid Amide" was false and misleading, and in that it was offered for sale under the name of another drug.

On September 15 and December 21, 1942, no claimant having appeared, judgments of condemnation were entered and the courts ordered that the article be delivered to the Florida State Hospital and to a State hospital at Milledgeville, Ga., after it had been relabeled under the supervision of the Food and Drug Administration.

#### DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS<sup>4</sup>

##### DRUGS FOR HUMAN USE

**821. Action to restrain interstate shipments of Catalyn and other drugs. U. S. v. Royal Lee (Vitamin Products Co.). Permanent injunction granted. (Inj. No. 12.)**

On June 19, 1941, the United States attorney for the Eastern District of Wisconsin filed a complaint against Royal Lee, trading as Vitamin Products Co., Elm Grove, Wis., alleging: (1) That the defendant was engaged in the manufacture, processing, and packing of vitamin and mineral products at Milwaukee, Wis., for introduction and delivery for introduction, distribution, and sale in interstate commerce under the firm name Vitamin Products Co. (2) That in connection with such business the defendant had designated, appointed, directed, and managed agents and distributors located in various cities in the United States and Canada and was continuing to do so. (3) That the following products, Catalyn, also known as V-P No. 710 Vitamin Tablets; V-P Vitamin A Complex, also known as V-P No. 711 Vitamin Tablets; V-P Vitamin B complex, also known as V-P No. 712 Vitamin Tablets; V-P Vitamin C Complex, also known as V-P No. 713 Vitamin Tablets; V-P Vitamin D Complex, also known as V-P No. 714 Vitamin Tablets; V-P Vitamin F Complex, also known as V-P No. 716 Vitamin Tablets; V-P Vitamin G Complex, also known as V-P No. 717 Tablets; V-P Phosphate, also known as V-P No. 718 Liquid; Cerol, also known as V-P No. 719 Vitamin Tablets; V-P Organic Mineral Tablets, also known as V-P No. 721 Mineral Tablets; and Cerodyn, had been manufactured, processed, and packed by the defendant at Milwaukee, Wis., and had been and were being introduced and delivered for introduction into interstate commerce by the defendant at Milwaukee, Wis., to his agents and distributors for sale, were being sold to the public, and remained in interstate commerce under the direction and control of the defendant.

The complaint alleged further that the product "Catalyn," also known as V-P No. 710 Vitamin Tablets, was fabricated from more than two active ingredients, namely, wheat flour, wheat bran, crystalline milk sugar, powdered rice bran, powdered carrots, and glandular material; that the product V-P Vitamin A Complex, also known as V-P No. 711 Vitamin Tablets, was fabricated from more than two active ingredients, namely, wheat starch and tissues, rice bran, root tissues resembling those of dried carrot, milk sugar, and animal tissues suggestive of glandular material; that the product V-P Vitamin B Complex, also known as V-P No. 712 Vitamin Tablets, was fabricated from more than two active ingredients, namely, wheat tissues and starch, rice bran, animal tissues apparently from

<sup>4</sup> See also Nos. 801, 805-809, 811-820.