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

2310. Adulteration and alleged misbranding of drug tablets. U. S. v. Charles H. Dietz, Inc. Motion to dismiss overruled. Plea of guilty to counts charging adulteration; fine, $350. Counts charging misbranding dismissed. (F. D. C. No. 20116. Sample Nos. 10249–H, 10484–H, 13723–H, 16765–H, 18526–H, 18554–H, 20078–H.)

INFORMATION FILED: July 22, 1946, Eastern District of Missouri, against Charles H. Dietz, Inc., St. Louis, Mo.

ALLEGED SHIPMENT: Between the approximate dates of January 12, 1944, to March 17, 1945, from the State of Missouri into the States of Pennsylvania, Ohio, Illinois, Minnesota, Nebraska, and Arkansas.

LABEL, IN PART: "Special Chocolate Coated Tablets R/3081 * * * Manufactured for McAdams Bros. Pittsburgh, Pa.," "Tablet Sugar Coated Red Strychnine Sulphate * * * Charles H. Dietz, Inc.," "Special Compressed Tablets Rx 2743 Pink * * * Manufactured for Jones Surg. Sup. Co., Cleveland, Ohio," "C. T. Acetanilide Comp. R/3099 * * * Manufactured for I. H. Scheef & Co. La Grange, Ill.," "Special Enteric Red Tablet Rx/2528 * * * Manufactured for Physicians and Hospitals Supply Co., Minneapolis, Minn.," "Special SC Red Tablet Rx 2752 * * * Manufactured for McDonald Pharm. Co. St. Paul, Minn.," or "Enteric SC Red Tablet R/2940 * * * Manufactured for Master Labs., Inc. Omaha, Nebr."

NATURE OF CHARGE: Adulteration, Section 501 (b), the *strychnine sulfate tablets* purported to be and were represented as a drug, the name of which, "Strychnine Sulphate Tablets," is recognized in the United States Pharmacopoeia, an official compendium, and their strength differed from the standard set forth therein, since they were represented as containing in each tablet 1/60th of a grain of strychnine sulfate, as determined by the methods of assay set forth in the compendium, whereas the article contained a lesser amount of strychnine sulfate. Further adulteration, Section 501 (c), the strength of the other tablets involved differed from that which they purported and were represented to possess. The representations made on the labels of these tablets were as follows: That the *Special Chocolate-Coated Tablets R/3081* contained 2 grains of sodium bicarbonate; that the *Special Compressed Tablets Rx 2743* contained ½ grain of caffeine alkaloid; that the *C. T. Acetanilide Comp. Tablets R/3099* contained 1 grain of acetanilide, ½ grain of caffeine alkaloid, 1 grain of sodium bromide, 1 grain of sodium salicylate, and 1 grain of sodium bicarbonate; that the *Special Enteric Red Tablet Rx/2528* contained 1 grain of sodium nitrite; that the *Special SC Red Tablet Rx 2752* contained 1/50 grain of arsenious acid and 1/60 grain of strychnine sulfate; and that the *Enteric SC Red Tablet R/2940* contained 1.932 grains of nicotine sulfate. The tablets contained less than the declared amounts of these ingredients.

Misbranding, Section 502 (a), the labels of the tablets, which represented that the tablets contained the amount of the ingredients indicated above, were charged to be false and misleading because of deficiency in the amount of these ingredients in the tablets.

DISPOSITION: On September 30, 1946, a motion to dismiss was filed on behalf of the defendant, and on November 21, 1946, suggestions in support thereof were filed, arguing in substance that each count failed to charge an offense, because the amount of shortage was not alleged in each instance. It was argued further that counts 2, 4, 6, 8, 10, 12, and 14 were duplicitous in that they charged misbranding of the respective products charged to be adulterated in counts 1, 3, 5, 7, 9, 11, and 13, and that such alleged adulteration and misbranding constitutes but one offense in the case of each product. In addition, a motion for a bill of particulars was subsequently filed for the defendant. On December 6, 1946, the court overruled the defendant's motion to dismiss and sustained the motion for a bill of particulars to the extent of requiring that the Government state the date of the Government's analysis of each tablet involved and the result obtained by such analysis. A bill of particulars was accordingly filed on December 13, 1946. Thereafter, on motion of the Government, the counts

*See also Nos. 2303, 2307.

of the information covering the misbranding charges were dismissed. A plea of guilty was entered to the remaining counts, and on May 29, 1947, the court imposed a fine of $50 on each of the 7 counts.

2311. Adulteration and misbranding of Diet Tablets. U. S. v. National Drug Laboratories, Inc., and Jules Press. Pleas of guilty. Fines, $2,000 and costs against corporation and $250 and costs against individual. (F. D. C. No. 23219. Sample No. 65559–H.)

INFORMATION FILED: October 6, 1947, Northern District of Illinois, against the National Drug Laboratories, Inc., Chicago, Ill., and Jules Press, president of the corporation.

ALLEGED SHIPMENT: On or about April 29, 1946, from the State of Illinois into the State of Pennsylvania.

LABEL, IN PART: "Diet Tablets * * * Distributed by Vitamix Corporation Philadelphia, Pa."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, in that each tablet was represented to contain 1/360 grain of atropine sulfate, whereas each tablet contained more than 1/360 grain of atropine sulfate.

Misbranding, Section 502 (a), the label statement "Atropine Sulphate 1/360 grain" was false and misleading.

The information alleged also that certain other products were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 29, 1948. Pleas of guilty having been entered, the court imposed fines of $2,000 and costs against the corporation and $250 and costs against the individual.

2312. Adulteration and misbranding of thyroid powder. U. S. v. 1 Drum * * * (and 1 other seizure action). (F. D. C. Nos. 24326, 24327. Sample Nos. 13039–K, 13040–K.)

LIBELS FILED: On or about February 2 and 10, 1948, District of New Jersey and Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 17 and 20, 1947, by the National Drug Laboratories, Inc., from Chicago, Ill.

PRODUCT: 1 300-pound drum and 1 100-pound drum of *thyroid powder* at Wenonah, N. J., and Philadelphia, Pa., respectively.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, thyroid, the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from, and its purity fell below, the official standard, since it contained less than 0.17 percent of iodine in thyroid combination and was not free from iodine in inorganic combination; and, Section 501 (d), a substance, iodine in a combination other than that peculiar to the thyroid gland, had been mixed and packed with the article so as to reduce its quality and strength, and had been substituted in part therefor.

Misbranding, Section 502 (i) (2), the article was an imitation of another drug, thyroid; and, Section 502 (i) (3), it was offered for sale under the name of another drug, thyroid.

DISPOSITION: March 5 and April 5, 1948. Default decrees of condemnation and destruction.

2313. Adulteration of elixir of phenobarbital. U. S. v. Herman Achs (Certified Laboratories). Plea of guilty. Defendant fined $100 and sentenced to 6 months in jail. Jail sentence suspended. (F. D. C. No. 23236. Sample No. 65188–H.)

INFORMATION FILED: September 18, 1947, Eastern District of Pennsylvania, against Herman Achs, trading as Certified Laboratories, Philadelphia, Pa.

ALLEGED SHIPMENT: On or about October 3, 1946, from the State of Pennsylvania into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance consisting essentially of an aqueous alcoholic solution containing phenobarbital, glycerin, saccharin, and cudbear, together with an aromatic material resembling orange oil, had been substituted for "Elixir of Phenobarbital," a drug the name of