282. Misbranding of Flu-Go. U. S. v. 9 Dozen Retail Packages of Flu-Go. Default decree of condemnation and destruction. (F. D. C. No. 2389. Sample No. 20240–E.)

The label of this product, in addition to failure to bear adequate warnings, also created the false and misleading impression that it was efficacious as a treatment for flu. Furthermore, the bottle occupied only approximately 37 percent of the space of the carton in which it was packed, and the quantity of contents was not declared.

On or about July 23, 1940, the United States attorney for the Eastern District of South Carolina filed a libel against 9 dozen retail packages of Flu-Go, alleging that the article had been shipped in interstate commerce on or about January 22, 1940, by the Flu-Go Chemical Co. from Bessemer, Ala.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of mineral oil, ephedrine, and aromatics including camphor and rose oil.

It was alleged to be misbranded in that the name "Flu-Go" created the false and misleading impression that it constituted a treatment for influenza; in that the label did not bear an accurate statement of the quantity of the contents; in that the labeling did not bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration or application; and in that its container was so made, formed, or filled as to be misleading.

On August 18, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS OR BECAUSE OF SUBSTITUTION[1]

VITAMIN PREPARATIONS

283. Misbranding of Old Man Frantz Mountain Tonic. U. S. v. Charton C. Frantz (Old Man Frantz). Plea of guilty. Fine, $100 and costs. (F. D. C. No. 961. Sample No. 78890–D.)

This product was labeled to indicate that it contained vitamins A and D in amounts sufficient to be of importance in conditions requiring administration of such vitamins; whereas it did not. Its labeling also bore false and misleading representations regarding its efficacy in the conditions indicated below.

On May 27, 1940, the United States attorney for the Western District of Pennsylvania filed an information against Charton C. Frantz, trading as Old Man Frantz at Pittsburgh, Pa., alleging shipment on or about November 17, 1939, from the State of Pennsylvania into the State of Ohio of a quantity of Old Man Frantz Mountain Tonic which was misbranded.

Analysis showed that the article consisted largely of water with small amounts of sugars, alcohol, salicyclic acid, cellular plant matter including starch, and a trace of oil. Tests showed that it contained 6 U. S. P. units of vitamin A and 1 U. S. P. unit of vitamin D per cc.

The article was alleged to be misbranded in that the statements, "Contains Vitamins A * * * D * * * Dosage: 1 oz. Each day for normal persons. 2 oz. Each day for those who require an extra amount of Vitamins," borne on the bottle label, were false and misleading in that they represented that the article, in the dosages recommended, would supply the user with vitamins A and D in amounts sufficient to be of importance in conditions requiring the administration of vitamins A and D; whereas the article, in the dosages recommended, would supply the user with not more than one-ninth the amount of vitamin A required by an audit, and not more than one-tenth the minimum dose of vitamin D recommended by the United States Pharmacopoeia.

Misbranding was alleged further in that certain statements in the circular were false and misleading in that they represented that the article was efficacious to increase pep, vim, vigor, and vitality, and would "build up"; that it was a tonic for run-down feeling, nervousness, lack of appetite, and lack of vigor and ambition; that it would aid in maintaining resistance in infections, and would increase the life span; that it was efficacious for poor appetite, dry skin, diarrhea, poor teeth, sterility, weakness, and would stimulate appetite, aid digestion

[1] See also No. 281.

and assimilation; that it was efficacious for poor lactation, atrophy of glands, gastric atony, and head retraction; that it would improve the appetite, stimulate growth essential to tissue respiration; that it contained ingredients essential for glandular functions; that it was efficacious for poor resistance to infections, restlessness, digestive disturbances, headache; that it would exert a beneficial influence in cases of low fertility, poor lactation, and failure of male germ cells to develop; that it was an antipellagric, would improve growth, promote health, prolong the active life span; that it was essential in nerve tissues; that it was efficacious in conditions which impair growth and shorten the life span, and was efficacious in the treatment of dermatitis, breakdown of the central nervous system, loss of hair, ulceration of tongue, loss in body weight of intestines and atony; whereas it would not be efficacious for such purposes.

On October 7, 1940, the defendant entered a plea of guilty and the court imposed a fine of $100 and costs.

284. Adulteration and misbranding of vitamin tablets. U. S. v. Royal Manufacturing Co. of Duquesne, Kolomon Kovacs, Samuel S. Kovacs, and Martin Kovacs. Pleas of nolo contendere. Dismissed as to the corporation. Fine of $25 and costs imposed against each individual defendant. (F. D. C. No. 945. Sample No. 55534–D.)

This product was found to contain less than one-sixtieth the amount of vitamin A and less than one-half the amount of vitamin D delcared on the label.

On April 15, 1940, the United States attorney for the Northern District of Illinois filed an information against the Royal Manufacturing Co. of Duquesne, Chicago, Ill., Kolomon Kovacs, Samuel S. Kovacs, and Martin Kovacs, alleging shipment on or about August 18, 1939, from the State of Illinois into the State of Michigan of a quantity of vitamin tablets that were adulterated and misbranded. The article was labeled in part "Saxon Six Vitamins in Tablet Form."

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported or was represented to possess in that each of said tablets was represented to contain not less than 3,138 U. S. P. units of vitamin A and not less than 314 U. S. P. units of vitamin D; whereas each tablet contained not more than 50 U. S. P. units of vitamin A and not more than 150 U. S. P. units of vitamin D.

It was alleged to be misbranded in that the statements, "Each Tablet Contains Not Less Than: Vitamin A, 3138 U. S. P. units * * * Vitamin D, 314 U. S. P. units * * * Vitamin C," borne on the carton, and "Directions: Adults take two to four tablets daily. Children one to three tablets daily," borne on the bottle label, were false and misleading in that they represented that each of said tablets contained not less than 3,138 U. S. P. units of vitamin A and not less than 314 U. S. P. units of vitamin D and that when taken according to directions would provide a substantial amount of vitamin C; whereas the said tablets contained less than 3,138 U. S. P. units of vitamin A and less than 314 U. S. P. units of vitamin D, and when taken in accordance with directions would not supply a substantial amount of vitamin C in that four tablets would supply less than one-tenth the amount of vitamin C required daily by adults, and three tablets would supply less than one-seventh the amount of vitamin C required daily by children less than 1 year old and less than one-tenth the amount required daily by children 1 to 12 years old.

On November 28, 1940, pleas of nolo contendere were entered. The court, after the facts had been presented and arguments of counsel had been heard, suggested that the defendant corporation be dismissed and, upon motion of the United States attorney, the case against the corporation was dismissed. Fines of $25 and costs were imposed against each individual defendant, with the provision that payment of the fine on the first count satisfy both counts.

285. Adulteration and misbranding of Nuval-Aid. U. S. v. 5 Dozen Bottles of Nuval-Aid. Default decree of condemnation and destruction. (F. D. C. No. 3658. Sample No. 50037–E.)

This product consisted essentially of sugar-coated yeast tablets. It contained not more than 36 U. S. P. units (International Units) of vitamin B_1 per tablet which was only three-fourths of the amount declared on the label.

On January 11, 1941, the United States attorney for the District of Columbia filed a libel against 5 dozen bottles of Nuval-Aid at Washington, D. C., alleging that the article had been shipped in interstate commerce on or about September 18, 1940, by V. M. Products from Chicago, Ill.; and charging that it was adulterated and misbranded.