

United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the Food and Drugs Act]

20551-20600

[Approved by the Acting Secretary of Agriculture, Washington, D.C., January 20, 1934]

20551. Adulteration and misbranding of effervescent Caf-Acetan, blue mass pills, sodium cacodylate ampoules, arsenous acid tablets, salol tablets, and fluidextract of squill. U.S. v. John Wyeth & Bro., Inc. Plea of nolo contendere. Fine, \$200. (F. & D. no. 28184. I.S. nos. 42733, 42862, 42874, 43711, 43738, 48766, 48768.)

This case was based on shipments of various pharmaceuticals in the form of pills, ampoules, or tablets which contained smaller amounts of the essential drugs than declared on the labels; of a shipment of so-called "headache salts" designated as effervescent Caf-Acetan which contained less acetanilid than declared, and of a shipment of fluidextract of squill represented to be of pharmacopoeial strength, which upon examination was found to possess less than one half the strength required by the United States Pharmacopoeia for the article.

On January 9, 1933, the United States attorney for the Eastern District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid an information against John Wyeth & Bro., Inc., Philadelphia, Pa., alleging shipment by said company in violation of the Food and Drugs Act, between the dates of August 24, 1931 and February 16, 1932, from the State of Pennsylvania into the States of New York and New Jersey, respectively, of quantities of Caf-Acetan, blue mass pills, sodium cacodylate ampoules, arsenous acid tablets, salol tablets, and fluidextract of squill, which products were adulterated and misbranded. The articles were labeled in part, variously: "Wyeth's Effervescent Caf-Acetan Headache Salts Containing 10 Grains Acetanilide in Each Ounce John Wyeth & Brother, Incorporated, Philadelphia, Pa."; "Gelatine-Coated Pill Blue Mass 5 Grains"; "12 1 cc. Ampoules * * * Sodium Cacodylate"; "Triturate 100 Arsenous Acid 1-60 Grain"; "Moulded Triturate 100 Arsenous Acid Arsenic Trioxide 1-100 Grain"; "Compressed Tablet Salol 5 Grains"; "Fluid Extract Squill U.S.P. 10th Revision."

Adulteration was alleged in the information for the reason that the strength and purity of the articles fell below the professed standard and quality under which they were sold, as follows: Each ounce of the effervescent Caf-Acetan was represented to contain 10 grains of acetanilid, whereas each ounce of the article contained not more than 8.4 grains of acetanilid. Each of the blue mass pills was represented to contain 5 grains of blue mass, whereas each of said pills contained not more than 3.662 grains of blue mass. Each ampoule of sodium cacodylate was represented to contain 1 cubic centimeter of solution of sodium cacodylate, whereas each of said ampoules contained less than 1 cubic centimeter of solution of sodium cacodylate. Each of the arsenous acid tablets was represented to contain one sixtieth of a grain or one one hundredth of a grain of arsenous acid, whereas the tablets which were represented to contain one sixtieth of a grain of arsenous acid contained not more than 0.0147 grain of the said drug, and the tablets which were represented to contain one one hundredth of a grain of arsenous acid contained not more than 0.0085 grain of the drug. Each of the salol tablets was represented to contain 5

grains of salol, whereas each of the said tablets contained not more than 4.287 grains of salol. The fluidextract of squill was represented to conform to the standard laid down in the United States Pharmacopoeia, tenth revision, whereas it did not. Adulteration of the fluidextract of squill was alleged for the further reason that it was sold under a name recognized in the United States Pharmacopoeia, and differed from the standard of strength, quality, and purity as determined by the test laid down in the said pharmacopoeia official at the time of investigation, in that 1 cubic centimeter of the product corresponded to 0.37 milligram of ouabain, whereas the pharmacopoeia provided that 1 cubic centimeter of fluidextract of squill should correspond to 0.83 milligram of ouabain; and the standard of strength, quality, and purity of the article was not declared on the container thereof.

Misbranding was alleged for the reason that the following statements appearing in the labeling of the respective products were false and misleading: "Effervescent Caf-Acetan * * * Containing 10 Grains Acetanilide in Each Ounce"; "Pill Blue Mass 5 Grains"; "1 cc. Ampoules * * * Sodium Cacodylate"; "Moulded Triturate * * * Arsenous Acid 1-60 Grain"; "Triturate * * * Arsenous Acid Arsenic Trioxide 1-100 Grain"; "Tablet Salol 5 Grains"; "Fluid Extract Squill U.S.P. 10th Revision."

On March 20, 1933, a plea of nolo contendere to the information was entered on behalf of the defendant company, and the court imposed a fine of \$200.

R. G. TUGWELL, *Acting Secretary of Agriculture.*

20552. Adulteration and misbranding of Lav-O-Din. U.S. v. The Lav-O-Din Co. Plea of guilty. Fine, \$150. (F. & D. no. 28068. I.S. no. 11161.)

Examination of samples of the drug preparation, Lav-O-Din contained in 4-, 8-, and 16-ounce bottles, disclosed that the article contained no ingredient or combination of ingredients capable of producing certain curative and therapeutic effects claimed in the labeling. It also was claimed for the article that it was an antiseptic, and that it was an iodine antiseptic, whereas it was not an antiseptic when used as directed, and contained no free iodine.

On September 23, 1932, the United States attorney for the Northern District of California, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid an information against the Lav-O-Din Co., a corporation, trading at Oakland, Calif., alleging shipment by said company in violation of the Food and Drugs Act as amended, in two consignments, on or about January 22 and March 17, 1931, from the State of California into the State of Oregon, of quantities of the said Lav-O-Din, which was adulterated and misbranded.

Analysis of a sample of the article by this Department showed that it consisted essentially of small proportions of potassium iodide, sodium chloride, borax, glycerin, alcohol (7.9 percent by volume), and water, flavored with cassia oil and colored with a red dye. Bacteriological examination showed that the article was not antiseptic.

It was alleged in the information that the article was adulterated in that its strength and purity fell below the professed standard and quality under which it was sold, in that it was represented to be an ideal and an iodine antiseptic, and that it could destroy germs when used as directed, whereas it was not an antiseptic when used as directed, and could not destroy the germs commonly present in the conditions for which it was prescribed.

Misbranding was alleged for the reason that the statements, "An Ideal Antiseptic No Germ Can Live In it", borne on certain of the cartons, and the statements, "An Iodine Antiseptic No Germ Can Live In It", borne on the remainder of the cartons and on the bottle labels, and the statements, "An Iodine Antiseptic No Germ Can Live In It, * * * its * * * antiseptic action, * * * an antiseptic, * * * In order to combat disease the germ must be destroyed, * * * It also guards against the germ-laden tooth brush", borne on the circular enclosed in the 4-ounce cartons, were false and misleading, since the article was not an antiseptic when used as directed, and could not destroy the germs commonly present in the conditions for which the product was prescribed. Misbranding was alleged for the further reason that certain statements, designs, and devices regarding the therapeutic and curative effects of the article, appearing on the bottle and carton labels, falsely and fraudulently represented that it was effective as a treatment, remedy, and cure for pyorrhea, trench mouth, spongy and bleeding gums, infections, wounds, cuts, boils, abscesses, carbuncles, running sores, erysipelas, itching eczema, piles in all forms,