

United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

76-140

DRUGS AND DEVICES

The cases reported herein were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by direction of the Secretary of Agriculture.

GROVER B. HILL, *Acting Secretary of Agriculture.*

Washington, D. C., May 8, 1940.

CONTENTS

	Page		Page
Misbranded sedatives, pain relievers, and headache remedies.....	33	Drugs labeled with false and misleading therapeutic claims.....	44
Drugs seized because of deviation from official or own standards or because of substitution.....	38	Drugs sold for both human and veterinary use.....	47
Vitamin preparations.....	38	Veterinary remedies.....	48
Miscellaneous.....	40	Drugs in deceptive containers.....	50
Drug seized because of contamination with filth.....	43	Nonsterile surgical dressings.....	52
		Prophylactics.....	56
		Index.....	61

MISBRANDED SEDATIVES, PAIN RELIEVERS, AND HEADACHE REMEDIES

76. Misbranding of Causalin. U. S. v. Amfre Drug Co., Inc., and Lewis Stern. Pleas of guilty. Fines, \$1,400. (F. D. C. No. 94. Sample Nos. 25962-D, 25963-D, 25964-D, 30071-D to 30074-D, incl., 30092-D to 30097-D, incl., 35452-D, 35453-D, 35367-D, 35569-D, 35570-D, 41997-D.)

This product consisted of capsules and tablets containing aminopyrine (aminodimethylpyrazolon,) salicylic ethyl ester carbonate, and a sulfonate such as quinolinesulfonate. It would be dangerous to health when used in the dosage or with the frequency prescribed, recommended, and suggested in the labeling.

The labeling of 6 of the 7 shipments bore the recommendation that the article be taken in the dosage as directed by the physician, 1 to 2 tablets or capsules 3 times a day, one-half hour before meals. In the seventh shipment the labeling in describing the "manner of use" of the article represented that the average dose was 1 capsule or tablet 3 times daily one-half hour before meals and that in severe or chronic cases one should start with 2 capsules or tablets 3 times daily continuing for about a week, then gradually reducing the dosage.

On January 30, 1940, the United States attorney for the Southern District of New York filed an information against the Amfre Drug Co., Inc., and Lewis Stern, president of the corporation, alleging shipment by said defendants within the period from on or about July 1 to on or about December 27, 1938, from the State of New York into the States of New Jersey, Pennsylvania, Massachusetts, and Rhode Island, of quantities of Causalin which was misbranded for the reasons appearing above.

The article was also charged with being adulterated and misbranded in violation of the Food and Drugs Act of 1906, reported in notice of judgment No. 80996, published under that act.

On January 30, 1940, pleas of guilty having been entered, the court imposed sentences for violation of both acts, the fines against each defendant on the counts charging violation of the Federal Food, Drug, and Cosmetic Act amounting to \$700.

77. Misbranding of Cal-co-cin. U. S. v. George T. Lambert, David Periera, and George D. Lambert. Pleas of nolo contendere. Fines, \$250. (F. D. C. No. 95. Sample Nos. 34424-D, 34642-D, 34644-D, 34708-D.)

This drug consisted of the calcium salts of benzoic acid and cinchophen. It would be dangerous to health when used in the dosage or with the frequency prescribed, recommended, and suggested in the labeling, which directed the dosage of one capsule four times a day, after meals and on retiring.

On September 13, 1939, the United States attorney for the Eastern District of Pennsylvania filed an information against George T. Lambert, David Periera, and George D. Lambert, trading as the Crescent-Kelvan Co., a business trust, Philadelphia, Pa., alleging shipment by said defendants within the period from on or about July 28 to on or about October 20, 1938, from the State of Pennsylvania into the State of Maryland of quantities of Cal-co-cin, which was misbranded in violation of the Federal Food, Drug, and Cosmetic Act for the reasons stated above.

The information also charged that the article was misbranded in violation of the Food and Drugs Act of 1906 reported in notice of judgment No. 30202 published under that act.

On December 8, 1939, pleas of nolo contendere were entered on behalf of the defendants. On January 5, 1940, the court imposed fines amounting to \$250 for violation of both acts.

78. Misbranding of Sodasal. U. S. v. Harry Enkel (Sodasal Laboratories). Plea of guilty. Sentence 1 year. Sentence suspended and defendant placed on probation for 3 years. Fine of \$100 also imposed. (F. D. C. No. 96. Sample Nos. 42944-D, 42971-D, 43181-D, 52224-D.)

This product contained aminopyrine, sodium salicylate, compounds of potassium, magnesium, and calcium, and citrates, carbonates, sugar, and water. It would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in the labeling, which directed that 1 tablespoonful or 4 teaspoonfuls be taken in water, milk, or orange juice, followed by a full glass of water or milk three times a day before or after meals or on retiring, and that the dose be cut down "if the ears ring or if allergic."

On November 14, 1939, the United States attorney for the Eastern District of Michigan filed an information against Harry Enkel, trading as the Sodasal Laboratories, Detroit, Mich., alleging shipment by said defendant within the period from on or about January 14 to on or about March 4, 1939, from the State of Michigan into the State of Pennsylvania of quantities of Sodasal which was misbranded for the reasons stated above.

The information also charged that the article was misbranded in violation of the Food and Drugs Act of 1906 reported in notice of judgment No. 80977 published under that act.

On December 4, 1939, a plea of guilty having been entered, the court sentenced the defendant to 1 year's imprisonment and imposed a fine of \$100 for violation of both acts. Prison sentence was suspended and the defendant was placed on probation for 3 years.

79. Misbranding of Hartshorn's Headache Powders. U. S. v. 89 Packages of Hartshorn's Headache Powders. Default decree of condemnation and destruction. (F. D. C. No. 618. Sample No. 69095-D.)

This product consisted essentially of acetanilid, caffeine, sodium bicarbonate, and flavoring materials. It would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling, which bore directions that 1 powder be taken, to be repeated in 20 to 30 minutes if necessary for simple headache; that 1 powder should be taken every 2 or 3 hours as required for simple neuralgia and acute rheumatic fever; that 1 powder be taken on retiring, to be repeated in 1 hour if sleep is not produced, for sleeplessness and nervousness; that 1 powder be taken and repeated in 1 hour, and 1 powder after 2 or 3 hours, for colds, and that not more than 3 powders should be taken during a period of 3 hours.