

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]

20876-20950

[Approved by the Acting Secretary of Agriculture, Washington, D.C., May 23, 1934]

20876. Adulteration and misbranding of Lav-O-Din. U. S. v. Western Chemical Co., Inc. Plea of guilty. Fine, \$100. (F. & D. no. 28071. I. S. nos. 13749, 21000, 25161.)

Examination of the drug preparation Lav-O-Din disclosed that it contained no ingredient or combination of ingredients capable of producing certain curative and therapeutic effects claimed on the cartons and bottles. The labels in certain of the shipments contained representations that the article was an antiseptic and would destroy germs, whereas it was not an antiseptic and would not destroy germs when used as directed.

On September 28, 1932, the United States attorney for the District of Minnesota, acting upon a report by the Secretary of Agriculture, filed in the district court of the United States an information against the Western Chemical Co., Inc., a corporation trading at Hutchinson, Minn., alleging shipment by said defendant in violation of the Food and Drugs Act, as amended, on or about June 13, 1930, and March 25, 1931, from the State of Minnesota into the State of Iowa, and on or about December 9, 1930, from the State of Minnesota into the State of Wisconsin, of quantities of Lav-O-Din that 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, carbonates, alcohol (7.8 percent by volume), and water, flavored with cinnamon oil. Bacteriological examination showed that the article was not antiseptic.

Adulteration was charged in the information with respect to portions of the article for the reason that its strength and purity fell below the professed standard and quality under which it was sold, that it was represented to be an antiseptic, and that it destroyed germs when used as directed; whereas it was not an antiseptic and would not destroy germs when used as directed.

Misbranding of the said portions was alleged for the reason that the statements, "Antiseptic", "No Germ Can Live In It", and "Kills Germs", borne on the cartons, were false and misleading. Misbranding was alleged for the further reason that certain statements, designs, and devices appearing on the bottle and carton labels, regarding the curative and therapeutic effects of the article, falsely and fraudulently represented that a portion of the article was effective as a treatment, remedy, and cure for wounds, cuts, boils, sore throat, tonsillitis, asthma, catarrh, hay fever, pyorrhea, eczema, spongy and bleeding gums, trench mouth, erysipelas, infections, abscesses, carbuncles, running sores, burns, itching eczema, piles in all forms, quinsy and nasal catarrh; effective as a dental treatment for pyorrhea and as a surgical dressing; effective as a preventive of pyorrhea and effective to retard tooth decay; and that the remainder was effective as a treatment, remedy, and cure for pyorrhea, trench mouth, spongy and bleeding gums, infections, wounds, cuts, boils, abscesses, carbuncles, running sores, burns, erysipelas, itching eczema, piles in all forms, sore throat, tonsillitis, quinsy and nasal catarrh, and effective as a surgical dressing.

On September 28, 1932, a plea of guilty to the information was entered on behalf of the defendant company, and the court imposed a fine of \$100.

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

20877. Misbranding of Sulphoradion. U. S. v. 67 Bottles of Sulphoradion. Default decree of condemnation, forfeiture, and destruction. (F. & D. no. 30002. Sample nos. 21688-A, 21689-A, 21690-A.)

Examination of the drug preparation Sulphoradion disclosed that it contained no ingredient or combination of ingredients capable of producing certain curative and therapeutic effects claimed on the bottle and carton labels.

On March 27, 1933, the United States attorney for the District of New Jersey, acting upon a report by the Secretary of Agriculture, filed in the district court of the United States a libel praying seizure and condemnation of 67 bottles of Sulphoradion at Newark, N.J., alleging that the article had been shipped in interstate commerce, on or about January 17, 1933, by the G. Sallusto Co., from Brooklyn, N.Y., to Newark, N.J., and charging misbranding in violation of the Food and Drugs Act as amended. The article was labeled in part: "Sulphoradion * * * Prepared by The Sulphoradion Co., Brooklyn, N.Y."

Analysis of a sample of the article by this Department showed that it consisted essentially of a thiocyanate such as sodium thiocyanate (3 grams per 100 milliliters), an iodide such as potassium iodide (2.7 grams per 100 milliliters), a nitrite such as sodium nitrite (0.2 gram per 100 milliliters), flavoring material, sugar, and water.

It was alleged in the libel that the article was misbranded in that the following statements regarding the curative or therapeutic effects of the article were false and fraudulent: (Bottle) "Sulphoradion * * * for High Blood Pressure Directions: One teaspoonful diluted in a half glass of water 3 times a day (one every five hours) until blood pressure is reduced to its optimal level. The dose is gradually reduced until the quantity required for maintenance is determined. This may be as low as one teaspoonful on alternate days. * * * Important: Observe Diet Suggested by Your Physician During and after Treatment to Maintain Normal Blood Pressure"; (carton) "Sulphoradion for High Blood Pressure * * * Directions: One teaspoonful in ½ glass of water 3 times a day (one every five hours until blood pressure is reduced to its optimal level. The dose is gradually reduced until the quantity required for maintenance is determined. This may be as low as one teaspoonful on alternate days. * * * To the Physician: * * * is especially recommended in the treatment of Hypertention and may be classed as a specific. Sulphoradion causes a fall in the blood pressure, especially in the systolic with usually no Change In The Rate Of the Heart. This fall will occur when the pressure is normal as well as when abnormally high. The best results are obtained in cases of 'Essential Hyperpiesis.' In patients showing much Kidney damage or arterio-sclerosis the effect is least evident but usually occurs to some extent. Dosage—Given in doses of one teaspoonful diluted in ½ glass of water 3 times daily 'Sulphoradion' will cause a significant fall in blood pressure after 4 to 8 days treatment. The systolic pressure is especially affected. Also the unpleasant symptoms associated with Hypertention such as headaches, nervousness and insomnia tend to be relieved, due in part to the sedative action of the drug in addition to the decrease in blood pressure. When the blood pressure is reduced to its optimal level the dose is gradually reduced until the quantity required for maintenance is determined. This may be as low as one teaspoonful on alternate days."

On April 24, 1933, no claimant having appeared for the property, judgment of condemnation and forfeiture was entered, and it was ordered by the court that the product be destroyed by the United States marshal.

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

20878. Misbranding of I-den-tine dental cream, Dr. Wayne's dental cream, and Orident dental cream. U. S. v. 47 5/6 Dozen Packages of I-den-tine Dental Cream, et al. Consent decree of condemnation, forfeiture, and destruction. (F. & D. nos. 29923, 29924, 29925. Sample nos. 20542-A, 20543-A, 20544-A.)

This case involved the interstate shipment of three brands of dental cream which, upon examination, were found to contain no ingredients or combinations of ingredients capable of producing certain curative and therapeutic effects claimed in the labeling. The articles also were falsely labeled as to name of the manufacturer, and in two of the brands as to the place of manufacture.

On March 13, 1933, the United States attorney for the Southern District of New York, acting upon a report by the Secretary of Agriculture, filed in the