

**2910. Misbranding of Therm-Massage Infra-Red Heat Applicator. U. S. v. 636
Cartons, etc. (F. D. C. No. 27259. Sample No. 60305-K.)**

LIBEL FILED: May 25, 1949, Eastern District of Michigan.

ALLEGED SHIPMENT: By Sibert & Co., from Newark, N. J. The device was shipped on or about December 3 and 8, 1948, and quantities of printed matter were shipped during the later part of 1948.

PRODUCT: 636 cartons each containing 1 *Therm-Massage Infra-Red Heat Applicator* at Dearborn, Mich., together with a number of display sheets entitled "Infra-Red Therm-Massage Heat Applicator," "Heat Massage Those Pains Away," and "Infra-Red Electric Heat Applicator," and a number of display cards entitled "Therm-Massage." The cartons containing the device were labeled with three different type labels, two of which contained the name of the manufacturer, Sibert & Co., and the third, pasted on by the consignee, contained the name of the distributor, the Ideal Sales Co.

Examination of the device showed that it consisted of two pieces of molded plastic, one serving as the handle and the other containing an electrically heated coil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on some of the cartons containing the device, on the display sheets, and on the display cards, were false and misleading. These statements represented and suggested that the device would be efficacious in the cure, mitigation, and treatment of colds, sinus, rheumatic pains, muscular aches and pains, stiff neck, sore throat, pains in the back, sprains, bruises, leg cramps, headache, arthritis, aching joints, neuralgia, rheumatism, neuritis, aching muscles, foot cramps, head pains, and back sprains, and that the device would help to prevent wrinkles and eliminate muddy complexion and skin blemishes. The device would not fulfill the promises of benefit stated and implied. The device was misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), certain statements on the cartons which had been relabeled, namely, "Colds - Sinus Rheumatic Pains Muscular Aches & Pains Stiff Neck - Sore Throat Pains in Back," were false and misleading since the device would not fulfill the promises of benefit stated and implied. The device was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: September 26, 1949. The Ideal Sales Co., Dearborn, Mich., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the devices were ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

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FEDERAL SECURITY AGENCY

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]

2911-2930

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *May 4, 1950.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 2912, 2929; failure to bear a label containing an accurate statement of the quantity of the contents, No. 2912; labeling information not likely to be understood by the ordinary individual under customary conditions of purchase and use, No. 2916.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2911. Misbranding of Nue-Ovo. U. S. v. 516 Cases * * *. Tried to the court. Verdict for the Government. Decree of condemnation and destruction. (F. D. C. No. 23385. Sample No. 70859-H.)

LABEL FILED: July 30, 1947, Southern District of California.

ALLEGED SHIPMENT: On or about March 18 and April 2 and 23, 1947, by Research Laboratories, Inc., from Portland, Oreg.

PRODUCT: 516 cases, each containing 18 1-pint bottles, of *Nue-Ovo* at Los Angeles, Calif.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the only directions appearing in the labeling, namely, "Directions for use of *Nue-Ovo* For Adults and Children over 10 Years of Age: Take (1) tablespoonful undiluted immediately before each meal and four (4) tablespoonfuls just before retiring. For Children 7 to 10 Years of Age: One-half of adult dose. Do not give to children under 7 years except on the advice of a physician. Shake Well Before Using," were inadequate in that the directions failed to reveal the diseases or conditions of the body for which the article when used as directed would be effective.

DISPOSITION: March 1, 1948. Research Laboratories, Inc., filed an answer denying that the product was misbranded and alleging as an affirmative defense that the Research Laboratories, Inc., was the owner of the product and was holding it in storage at a warehouse at Los Angeles, Calif.; that the product was to be labeled or repacked in substantial quantities at an establishment other than where it was originally processed; and that the Research Laboratories, Inc., was the operator of the establishment where the article was to be labeled or repacked.

The case came on for trial before the court without a jury on April 27, 1948, and was concluded on the same day with a verdict for the Government. On May 13, 1948, findings of fact and conclusions of law were filed in accordance with such verdict, and judgment was entered providing for condemnation and destruction of the product. On July 2, 1948, a stay of execution was granted pending final disposition by the United States Supreme Court of the petition for certiorari, which had been filed in the case reported in notices of judgment No. 2921. Following denial of certiorari, action was taken in regard to the execution of the judgment of May 13, 1948, resulting in the destruction of the product on January 19, 1949.

2912. Misbranding of nembutal capsules. U. S. v. Katz Drug Co. Plea of nolo contendere. Fine, \$375. (F. D. C. No. 25609. Sample Nos. 68535-H to 68539-H, incl., 21167-K, 21168-K, 21175-K, 21176-K, 21182-K, 21184-K, 21185-K.)

INFORMATION FILED: June 28, 1949, Western District of Missouri, against the Katz Drug Co., a corporation, Kansas City, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of September 15 and October 22, 1947, from North Chicago, Ill., of quantities of *nembutal capsules*.

LABEL, WHEN SHIPPED: "Capsules Nembutal Pentobarbital Sodium * * * 1½ grs. * * * Caution: To be dispensed only by or on the prescription of a physician or dentist."