## 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.)

LIBEL 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."

ALLEGED VIOLATION: Between February 11 and March 26, 1948, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of capsules of the drug to be repacked into bottles and to be sold to various persons without a prescription, which acts of the defendant resulted in the capsules being misbranded. The repackaged capsules were labeled "Katz Drug Co * * * Kansas City, Missouri No. 317745 Dr. McCracken One at bed time for sleep if needed."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the label failed to bear the common or usual name of the drug, "pentobarbital sodium"; Section 502 (d), the repackaged drug was for use by man and contained a chemical derivative of barbituric acid, which derivative had been found, by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as habit forming, and the label failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith, the statement "Warning—May be habit forming"; and, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use since the directions for use on the labeling "One at bed time for sleep if needed" were not adequate directions.

DISPOSITION: November 7, 1949. A plea of nolo contendere having been entered, the court imposed a fine of $375.

**2913. Misbranding of Fruitonya, Neutraton, Hematon No. 1, Hematon No. 2, Phospho B Complex, Ribo Ton, and Java Ton. U. S. v. 144 Bottles, etc.** (F. D. C. No. 24730. Sample Nos. 2029-K, 2030-K, 2032-K to 2036-K, incl.)

LIBEL FILED: April 15, 1948, District of Columbia; libel amended October 12, 1948.

ALLEGED SHIPMENT: By the Miracle Food Co., from Philadelphia, Pa.

PRODUCT: 144 1-quart bottles of *Fruitonya;* 24 13-ounce cans of *Neutraton;* 24 16-ounce bottles of *Hematon No. 1;* 24 75-tablet boxes of *Hematon No. 2;* 24 50-capsule boxes of *Phospho B Complex;* 24 100-tablet boxes of *Ribo Ton;* and 24 4-ounce cans of *Java Ton* at Washington, D. C.

The products were advertised for various diseases, symptoms, and conditions at lectures given by J. D. Levine at Washington, D. C., on April 5, 6, and 12, 1948.

LABEL, IN PART: "Fruitonya * * * Contains invert sugar, True fruit extracts, Reinforced with Natural flavors & fruit acids"; "Neutraton * * * Contains Lactose, Skimmed Milk, Dicalcium phosphate, Irradiated Milk, Whey Powder"; "Hematon No. 1 * * * Three teaspoonfuls provide: Vitamin A . . . 5,000 U. S. P. Units, Vitamin D . . . 1,200 U. S. P. Units, Vitamin $B_1$ (Thiamin) . . . 1 mg., Vitamin $B_2$ (G) (Riboflavin) . . . ½ mg., Niacinamide . . . 10 mg., Green Iron & Ammon. Citrate . . . 3 grs., Iron . . . 30 mgs."; "Hematon No. 2 * * * Each tablet Contains: 2,500 U. S. P. Units Vitamin A, 250 U. S. P. Units Vitamin D, ½ Mgm. Colloidal Copper, 5 Mgm. Iron"; "Phospho B Complex * * * Contains: Vitamin $B_1$ (Thiamin Chloride) 500 U. S. P. Units, Vitamin $B_2$ (Riboflavin) 2,000 Micrograms, Vitamin $B_6$ (Pyridoxine) 30 Micrograms, Calcium Pentothenate 250 Micrograms, Niacin Amide 10,000 Micrograms, Lectithin (Inert Amt.) 10,000 Micrograms"; "Ribo Ton * * * A Tablet Contains: Carrot Powder, Parsley Powder, Spinach Powder, 500