

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]

2501-2550

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 direction of the Federal Security Administrator.

J. DONALD KINGSLEY, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *February 28, 1949.*

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

2501. Misbranding of seconal sodium capsules and amytal tablets. U. S. v. Harry Skepner (Harry Skepner Prescription Pharmacy). Plea of nolo contendere. Defendant fined \$2,000 and sentenced to 1 year's imprisonment. Prison sentence suspended for period of 3 years and defendant placed on probation. (F. D. C. No. 24261. Sample Nos. 44830-H, 44831-H.)

INFORMATION FILED: April 27, 1948, Southern District of California, against Harry Skepner, trading as Harry Skepner Prescription Pharmacy at Hollywood, Calif.

ALLEGED SHIPMENT: On or about May 7, 1947, from the State of California into the State of Arizona.

LABEL, IN PART: "Harry Skepner Rx Prescription Pharmacist Rx Sick Room Supplies 6255 Hollywood Blvd. Hollywood, Calif."

*For presence of a habit-forming narcotic without warning statement, see No. 2501; omission of, or unsatisfactory, ingredients statements, Nos. 2502, 2513, 2516, 2540, 2541, 2543, 2546, 2547, 2549; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2501, 2503, 2508, 2528, 2541, 2543, 2546; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2541; cosmetics, subject to the drug provisions of the Act, Nos. 2502 (Rensom Liquid Antiseptic Skin Lotion and Rensom Soothing Emollient), 2528 (Thi-Cin Cream and Q-2 Cream), 2540 (Yuth).

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the articles bore no label containing a statement of the quantity of the contents; Section 502 (d), they were 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 regulation 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 articles bore no directions for use.

DISPOSITION: July 7, 1948. A plea of nolo contendere having been entered, the court imposed a fine of \$1,000 and a sentence of 1 year's imprisonment on count 1. The prison sentence was suspended for a period of 3 years and the defendant was placed on probation, conditioned that the fine be paid and that he not violate any Federal, State, or local laws. In addition, the court imposed a fine of \$1,000 on count 2 of the information.

2502. Misbranding of Mo-Tee-Na Special Tablets, Vaginal Salve, Rensom Liquid Antiseptic Skin Lotion, and Rensom Soothing Emollient. U. S. v. General Products Laboratories, Inc., Frederick L. Ferguson, and Jay G. Hobson. Pleas of guilty. Fine of \$400 against each defendant. (F. D. C. No. 24221. Samples Nos. 15227-H, 15228-H, 35794-H, 35795-H.)

INFORMATION FILED: February 20, 1948, Southern District of Ohio, against General Products Laboratories, Inc., Columbus, Ohio, Frederick L. Ferguson, president, and Jay G. Hobson, vice-president.

ALLEGED SHIPMENT: On or about January 16, May 17, and July 29, 1946, from the State of Ohio into the States of Illinois and Missouri.

LABEL, IN PART: "Mo Tee Na Special Tablets * * * Active Ingredients: Celery Seed, Passion Flower, Gentian, Ext. Nux Vomica $\frac{1}{4}$ grain per tablet"; "Vaginal Salve * * * Active Ingredients: Powdered Alum, Turpentine. Inactive Ingredients: Glycerin, Boric Acid, Iodine, Carbolic Acid 4.17% in Petrolatum Base"; "Rensom Liquid Antiseptic Skin Lotion * * * Active Ingredients: Iron Sulphate (Copperas), Boric Acid, Distilled water, Q. S."; and "Rensome Soothing Emollient * * * Active Ingredients: Red Precipitate, Zinc Oxide. Inactive Ingredients: White Petrolatum, Oil Sassafras."

NATURE OF CHARGE: "*Mo-Tee-Na Special Tablets*. Misbranding, Section 502, (a) the label statement "For Simple Nervousness, Sluggishness, and Lack of Energy Due to Overwork" was false and misleading, since the article would not be efficacious in the cure, mitigation, and treatment of simple nervousness, sluggishness, and lack of energy due to overwork.

Vaginal Salve. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the labeling failed to state the conditions, diseases, and functions for which the article was to be used.

Rensom Liquid Antiseptic Skin Lotion. Misbranding, Section 502 (a), the label statement "Antiseptic" was false and misleading, since it represented and suggested that the article was an antiseptic, whereas it was not an antiseptic within the meaning of the law, in that it was not a germicide when used in accordance with the directions appearing in the labeling and did not purport to be, and was not represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involved prolonged contact with the body. Further misbranding, Section 502 (f) (1), the directions contained in the labeling for use of the article in the treatment of wounds were inadequate, in that the article would only be of value in the treatment of minor wounds when used as a wet dressing and the directions did not provide for the use of the article as a wet dressing.

Rensom Soothing Emollient. Misbranding, Section 502 (a), the label statements "Promotes Healing of Certain Skin Irritations * * * To relieve Itching and Burning of Eczema, and many similar skin irritations of external origin" were false and misleading, since the article would not promote healing of skin irritations and would not relieve itching and burning of eczema and many similar skin irritations of external origin. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and it contained the ingredient, red precipitate, a derivative of mercury; the label of the article did not bear a statement showing the substance from which the