

# 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]

1751-1800

#### 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.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., October 28, 1946.

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#### DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

**1751. Adulteration and misbranding of vitamin B complex No. 2. U. S. v. 98 Vials of Vitamin B Complex No. 2. Default decree of condemnation and destruction.** (F. D. C. No. 16129. Sample No. 4457-H.)

**LABEL FILED:** May 10, 1945, Eastern District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about April 17, 1945, from New York, N. Y., by the Alpinol Corporation.

**PRODUCT:** 98 vials of *vitamin B complex No. 2* at Upper Darby, Pa. Examination showed that the product contained no thiamine or riboflavin. It possessed the characteristics of an oil, being immiscible with water. Oils or other materials not miscible with water, if injected into the veins, may cause serious injury or death.

**LABEL, IN PART:** "30 cc. Vial \* \* \* Vitamin B Complex No. 2 Each 1 cc. contains: Thiamin HCl . . . 20 mg. Riboflavin . . . 1 mg. \* \* \* . Intramuscular—Intravenous."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess and was represented to possess, namely,

\*For failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, see Nos. 1754, 1755, 1761, 1795, 1796; failure to comply with the packaging requirements of an official compendium, No. 1775; labeling information not likely to be understood by the ordinary individual, No. 1787; cosmetic, subject to the drug provisions of the Act, No. 1789.

"Each 1 cc. contains: Thiamin HCl . . . 20 mg. Riboflavin . . . 1 mg.," since the article contained no thiamine or riboflavin.

Misbranding, Section 502 (j), the article would be dangerous to health when used in the intravenous dosage recommended, suggested, and prescribed in the labeling.

**DISPOSITION:** October 11, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1752. Misbranding of Re-Sude-Oids. U. S. v. 49 Dozen Packages of Re-Sude-Oids. Default decree of condemnation and destruction. (F. D. C. No. 16375. Sample No. 17509-H.)**

**LABEL FILED:** June 25, 1945, Northern District of Illinois.

**ALLEGED SHIPMENT:** On or about May 18, 1945, from Los Angeles, Calif., by the American Medical Products, Inc.

**PRODUCT:** 49 dozen packages of *Re-Sude-Oids* at Chicago, Ill. Examination showed that the product contained approximately one-half grain each of thyroid and potassium iodide per capsule.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the label were false and misleading since they represented and suggested that the article was an appropriate and effective treatment for obesity due to hypothyroidism caused by deficient action of the thyroid gland, the pituitary gland, or the ovarian gland. The article was neither an appropriate nor an effective treatment for obesity, whether or not due to hypothyroidism resulting from such causes.

Further misbranding, Section 502 (j), the article would be dangerous to health, because of its content of thyroid, when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: (Carton) "When administering these capsules the dose for an average person, depending upon his requirements, may often be one capsule daily for six days, then one capsule twice a day for six days, then one capsule three times a day as long as treatment is continued"; (bottle label) "It is suggested that the dose for an average person, depending upon his requirements, may often be one capsule daily for six days, then one capsule twice a day for six days, then one capsule three times a day as long as treatment is continued."

**DISPOSITION:** October 30, 1945: No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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

**1753. Misbranding of Fentone Compound. U. S. v. Will T. Warren, Jr. (Fentone Medicine Co.). Plea of nolo contendere. Fine, \$2,000; jail sentence of 60 days. (F. D. C. No. 14250 Sample Nos. 41524-F, 61323-F.)**

**INFORMATION FILED:** June 13, 1945, Western District of Tennessee, against Will T. Warren, Jr., trading as the Fentone Medicine Co., Paris, Tenn.

**ALLEGED SHIPMENT:** Between the approximate dates of August 2 to September 22, 1943, from the State of Tennessee into the State of Mississippi.

**LABEL, IN PART:** "Blythe and Fentress Fentone Compound."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statement, "Liver & Bile Stimulant," and certain statements in the accompanying circulars were false and misleading since they represented and suggested that the article would be efficacious as a liver and bile stimulant and kidney flusher; that it would be efficacious in the correction of intestinal stasis, and would prevent the spreading of poisons throughout the system and the contamination of the blood stream, liver, and kidneys as a result of intestinal stasis; that it would cause the heart, stomach, intestines, bladder, lungs, liver, and kidneys to work perfectly and regularly; that it would be efficacious in removing deep-seated impurities from the stomach, acid deposits in the kidneys, and pockets of impurity; that it would remove excess acid and bacteria; that it would be efficacious to relieve back pains and bring about a feeling of new life and happiness; that it would be efficacious in the cure, mitigation, treatment, and prevention of high blood pressure, rheumatism, arthritis symptoms, nervousness, loss of sleep, backache, belching and bloating, spitting of burning, hot, half-digested food, pains in the back, stiffness in the joints, and tired, run-