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]

1801–1850

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., *December 6, 1946.*

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DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1801. Misbranding of Re-Sude-Oids. U. S. v. American Medicinal Products, Inc., and Ernest G. Rurup. Pleas of nolo contendere. Corporation fined $251; individual fined $1 and sentenced to 10 days in jail. The jail sentence was suspended and the individual placed on probation. (F. D. C. No. 12528. Sample Nos. 14456–F, 42658–F.)

INFORMATION FILED: October 2, 1944, Southern District of California, against the American Medicinal Products, Inc., Los Angeles, Calif., and Ernest G. Rurup, general manager. The defendants were charged with giving a false guaranty. The guaranty was given to McKesson & Robbins, Inc., New York, N. Y., on or about May 22, 1942. It provided that the article comprising each shipment or delivery made by the defendants to the latter firm would be neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. On or about March 29, 1943, the defendants sold and delivered to McKesson & Robbins at Los Angeles, Calif., a quantity of *Re-Sude-Oids* which

*For drugs actionable because of deceptive packaging, see No. 1801; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 1802, 1805, 1809, 1832, 1844; omission of, or unsatisfactory, ingredients statements, Nos. 1802–1809; presence of a habit-forming narcotic without warning statement, Nos. 1803, 1804; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 1809, 1844; cosmetics, subject to the drug provisions of the Act, No. 1841.

was shipped on or about April 12, 1943, by McKesson & Robbins, Inc., from the State of California into the State of Arizona.

In addition, it was charged that the defendants themselves shipped, on or about May 11, 1943, a quantity of *Re-Sude-Oids* from the State of California into the State of Oregon.

PRODUCT: Analysis showed that the product was composed essentially of inorganic and organic compounds of iodine, together with phenolphthalein, lactose, and dried animal tissue. The capsules in the two shipments contained, per capsule, an average of approximately ½ grain and 0.68 grain, respectively, of thyroid and an average of 1/50 grain and 1/48 grain of phenolphthalein.

LABEL, IN PART: "Re-Sude-Oids Capsules * * * Slight Change in Spelling the Name of this Product Same Formula * * * Thyroid ½ Grain Per Capsule Whole Pituitary Ovarian Extract Potassium Iodide Phenolphthalein."

NATURE OF CHARGE: Misbranding, Section 502 (j), the product would be dangerous to health when used in the dosage and with the frequency and duration prescribed in the following labeling: (Carton, bottle, and circular entitled "Re-Sude-Oids Capsules Method") "Take one capsule daily for six days, then one capsule twice [or "2 times"] a day for six days, then one capsule three times a day with all following bottles." The capsules of a portion of the product contained 0.68 grain and those in the remainder contained ½ grain of thyroid, which would render the use of the drug dangerous when consumed as directed.

Misbranding, Section 502 (a), the labeling was false and misleading since it represented that the product was a safe, appropriate, and effective remedy for obesity due to hypothyroidism caused chiefly by the deficient action of the thyroid gland and, sometimes, the pituitary and ovarian glands. The product was unsafe, dangerous, inappropriate, and ineffective as a treatment for such conditions. Further misbranding, Section 502 (a), the statement "Thyroid ½ Grain" was false and misleading with respect to the portion of the product that contained 0.68 grain of thyroid per capsule. Further misbranding, Section 502 (a), the labeling was misleading since it failed to reveal the fact that the amount of phenolphthalein in each capsule was too small to exert any material laxative action.

Misbranding, Section 502 (i) (1), the containers were so made, formed, and filled as to be misleading, since the bottles were filled to only 59.1 percent of their capacity and they occupied only 47.6 percent of the capacity of the cartons.

The information also charged the defendants with having shipped a misbranded food in interstate commerce, as reported in notices of judgment on foods.

DISPOSITION: May 14, 1945. Pleas of nolo contendere having been entered on behalf of the defendants, the corporation was fined $251, and the individual defendant was fined $1 and sentenced to 10 days in jail. The jail sentence was suspended and the individual was placed on probation until October 9, 1945, on condition that future sales of the product be made under labels which had been submitted by the defendants and approved by the court.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

1802. Adulteration and misbranding of Sulfa-Sino and Sulfa-Rub, and misbranding of Sulfa-Zema. U. S. v. Samuel R. Myerson (Sulfa-Septic Products). Plea of guilty. Fine, $1,000 and probation for 1 year. (F. D. C. No. 16543. Sample Nos. 61831-F to 61833-F, incl., 66962-F.)

INFORMATION FILED: November 14, 1945, Western District of Missouri, against Samuel R. Myerson, trading as Sulfa-Septic Products, Kansas City, Mo.

ALLEGED SHIPMENT: On or about April 29 and September 27, 1944, from the State of Missouri into the States of Texas and Kansas; two lots of *Sulfa-Sino* and one lot each of *Sulfa-Zema* and *Sulfa-Rub*.

PRODUCT: Analysis of a sample from one shipment of the *Sulfa-Sino* showed that it contained approximately 3 percent of sodium sulfathiazole. Qualitative analysis of a sample from the other shipment of the same product disclosed the presence of sulfathiazole, but the amount was not determined. Analysis showed that the *Sulfa-Zema* contained approximately 2.9 percent of sodium sulfathiazole in an ointment base; and that the *Sulfa-Rub* contained not more than 1.45 percent of sodium sulfathiazole and 95 percent of isopropyl alcohol.