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.

NATURE OF CHARGE: *Sulfa-Sino.* Adulteration, Section 501 (c), the strength of one shipment of the article differed from that which it purported and was represented to possess, since it was represented to contain 1 percent of ephedrine, whereas it contained no ephedrine. Misbranding, Section 502 (a), the name of the article and the statement on the label, "For the treatment of sinus infection and head colds," were false and misleading since they represented and suggested that the article would be efficacious in the treatment of sinus infection and head colds. The article would not be efficacious for such purposes. Further misbranding, Section 502 (f) (2), the labeling failed to bear a warning that use of the article should be discontinued if a general skin rash appeared or if the patient developed a fever or any other indication of illness, and it failed to warn that the article might sensitize its user to sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions; and, Section 502 (b) (2), one shipment of the article bore no label containing a statement of the quantity of the contents.

Sulfa-Zema. Misbranding, Section 502 (a), the name of the article and the statement on the label, "For treatment of Eczema, Psoriasis and other skin diseases," were false and misleading since they represented and suggested that the article would constitute an adequate treatment for eczema, psoriasis, and other skin diseases. The article would not constitute an adequate treatment for such conditions. Further misbranding, Section 502 (f) (2), the labeling failed to bear a warning that use of the article should be discontinued if the skin condition under treatment became worse, if a new rash appeared, or if the patient developed a fever or any other indication of illness, and it failed to warn that the article might sensitize its user to sulfonamides.

Sulfa-Rub. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, since it was represented to contain 3 percent of sulfathiazole sodium, whereas it contained not more than 1.45 percent of sulfathiazole sodium. Misbranding, Section 502 (a), the statements on the label, "For the treatment of * * * scalp infections * * * then use once weekly to keep hair and scalp clean and healthy," were false and misleading since they represented and created the impression that the article would be efficacious in the treatment of all scalp infections, and that use of the article once weekly would keep the hair and scalp clean and healthy. The article would not be efficacious for such purposes. Further misbranding, Section 502 (b) (2), the bottle containing the article bore no label containing a statement of the quantity of the contents; Section 502 (e) (2), the label failed to state the quantity, kind, and proportion of alcohol present in the article; and, Section 502 (f) (2), the labeling failed to bear a warning that use of the article should be discontinued if the skin condition under treatment became worse, if a general skin rash appeared, or if the patient developed a fever or any other indication of illness, and it failed to warn that the article might sensitize its user to sulfonamides.

Further misbranding, Section 505, the *Sulfa-Zema* and the *Sulfa-Rub* were new drugs which should not have been introduced into interstate commerce since they were not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions recommended and suggested in their labeling; and no application had been filed, pursuant to the law, with respect to the articles.

DISPOSITION: December 3, 1945. The defendant having entered a plea of guilty, the court imposed a fine of $500 on count 1, $250 on count 2, and $250 on count 7. Sentence was suspended on counts 3, 4, 5, and 6, and the defendant was placed on probation for 1 year.

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

1803. Misbranding of Seconal Sodium Capsules and Luminal Tablets. U. S. v. Marvin J. Jones, also known as Morgan Jones (Lewis Drug Store). Plea of guilty. Fine, $1,200. (F. D. C. No. 15523. Sample Nos. 90602–F, 90604–F to 90606–F, incl., 90608–F, 90611–F to 90613–F, incl.)

INFORMATION FILED: May 11, 1945, Southern District of Ohio, against Marvin J. Jones, also known as Morgan Jones, trading as the Lewis Drug Store, Jackson, Ohio.

*See also No. 1802.