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.

INTERSTATE SHIPMENT: Between the approximate dates of March 29 and July 25, 1944, from Indianapolis, Ind., and Chicago, Ill.; a number of bottles containing *Seconal Sodium Capsules* and *Luminal Tablets*.

LABEL, IN PART: (Bottle, when shipped) "5000 Pulvules Seconal Sodium 1½ grs. (0.1 Gm.) (Sodium Propyl-methyl-carbinyl Allyl Barbiturate, Lilly) Warning—May be habit forming Not For Intravenous Use Caution—To be used only by or on the prescription of a physician," or "50 Tablets Luminal Brand of Phenobarbital Warning—May Be Habit Forming Caution: To be used only by or on the prescription of a physician, dentist, or veterinarian."

NATURE OF CHARGE: That between August 25 and September 17, 1944, while they were being held for sale at the Lewis Drug Store, a number of *Seconal Sodium Capsules* were removed from the bottles in which they had been shipped and were repacked into smaller bottles bearing substantially the same labels; and that on or about September 16 and 17, 1944, the defendant removed a number of the capsules from the smaller bottles, repacked them in unlabeled envelopes, and sold them without a prescription. The information also charged that on or about September 17, 1944, the defendant removed a quantity of tablets from the bottle labeled "Tablets Luminal," repacked them into an unlabeled box, and sold them without a prescription.

The information charged further that the acts of the defendant resulted in the misbranding of the drugs in the following respects: Section 502 (d), the drugs contained a chemical derivative of barbituric acid, which derivative has been found to be and by regulations designated as habit forming, and their labels failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement, "Warning—May be habit forming"; Section 502 (f) (1) (2), the envelope and the box containing the drugs bore no labeling containing directions for use, and they bore no labeling containing warnings against use in those pathological conditions wherein the use of drugs might be dangerous to health, or against unsafe dosage and methods and duration of administration; and, Section 502 (e), the envelopes and the box containing the *Seconal Capsules* and the *Luminal Tablets*, respectively, failed to bear labels containing the common or usual names of the drugs, "Seconal" and "phenobarbital," respectively.

DISPOSITION: May 21, 1945. A plea of guilty having been entered, the court imposed a fine of $150 on each of the 8 counts of the information.

1804. Misbranding of Seconal Sodium Capsules and Luminal Tablets. U. S. v. John Edward Jones, also known as Jay Jones. Plea of guilty. Fine, $300. (F. D. C. No. 15524. Sample Nos. 90601–F, 90603–F, 90611–F.)

INFORMATION FILED: May 11, 1945, Southern District of Ohio, against John Edward Jones, also known as Jay Jones, Jackson, Ohio.

INTERSTATE SHIPMENT: Between the approximate dates of March 29 and July 25, 1944, from Indianapolis, Ind., and Chicago, Ill.; a number of bottles containing *Seconal Sodium Capsules* and *Luminal Tablets*.

LABEL, IN PART: (Bottle, when shipped) "5000 Pulvules Seconal Sodium 1½ grs. (0.1 Gm.) (Sodium Propyl-methyl-carbinyl Allyl Barbiturate, Lilly) Warning—May be habit forming Not For Intravenous Use Caution—To be used only by or on the prescription of a physician," or "50 Tablets Luminal Brand of Phenobarbital Warning—May Be Habit Forming Caution: To be used only by or on the prescription of a physician, dentist, or veterinarian."

NATURE OF CHARGE: That between the dates of August 25 and September 16, 1944, while they were being held for sale at the Lewis Drug Store, a number of the *Seconal Sodium Capsules* were removed from the bottles in which they had been shipped and were repacked in smaller bottles bearing substantially the same labels; and that on or about September 16, 1944, the defendant removed a number of the capsules from the smaller bottles, repacked them in unlabeled envelopes, and sold them without a prescription. The information also charged that on or about September 16, 1944, the defendant removed a quantity of tablets from the bottle labeled "Tablets Luminal," repacked them into a box unlabeled except for the words "Luminal 1½ gr.," and sold them without a prescription.

The information charged further that the acts of the defendant resulted in the misbranding of the drugs in the following respects: Section 502 (d), the drugs contained a chemical derivative of barbituric acid, which derivative has been found to be and by regulations designated as habit forming, and their labels failed to bear the name and quantity or proportion of such derivative and, in