

**ALLEGED VIOLATION:** On or about July 7, 21, and 25, and August 21 and 24, 1949, while a number of the above-mentioned capsules and tablets were being held for sale at the Harry W. Schaum Drug Co. after shipment in interstate commerce, various quantities of the capsules and tablets were repacked and sold without a prescription, which acts resulted in the repackaged tablets and capsules being misbranded.

The Harry W. Schaum Drug Co. was charged with causing the acts of repacking and sale of the drugs involved in each of the eight counts of the information; and, in addition, Harry W. Schaum, in four of the counts, and Howard H. W. Schulze, in the four other counts of the information, were charged with causing such acts to be done in connection with the drugs involved in those counts.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (1), a portion of the *sulfonamides triplex tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged drugs, with the exception of the *sulfonamides triplex tablets*, failed to bear labeling containing adequate directions for use since the directions for use "One at bedtime," borne on the labeling of the *pentobarbital sodium capsules*, were not adequate directions for use, and since the *Dexedrine Sulfate tablets* bore no labeling containing directions for use; and, Section 502 (f) (2), the labeling of the *sulfonamides triplex tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods of duration of administration.

**DISPOSITION:** June 12, 1950. A plea of guilty was entered on behalf of the company, and a plea of nolo contendere was entered on behalf of each individual defendant. The court, thereupon, imposed a fine of \$1,000 against the company, suspended the imposition of sentences against the individual defendants, and placed the individuals on probation for 1 year.

3167. Misbranding of sulfadiazine tablets, Seconal Sodium capsules, Dexedrine Sulfate tablets, and Ergoapiol with Savin capsules. U. S. v. Leroy M. Clayton (Jack Clayton Drug Store), and Paul E. Calmes. Pleas of guilty. File of \$200 against defendant Clayton and \$25 against defendant Calmes. (F. D. C. No. 29117. Sample Nos. 55801-K to 55808-K, incl.)

**INFORMATION FILED:** June 5, 1950, Western District of Oklahoma, against Leroy M. Clayton, trading as the Jack Clayton Drug Store, Clinton, Okla., and against Paul E. Calmes, pharmacist.

**INTERSTATE SHIPMENT:** From the States of Indiana, New York, and Pennsylvania, into the State of Oklahoma, of quantities of *sulfadiazine tablets*, *Seconal Sodium capsules*, *Ergoapiol with Savin capsules*, and *Dexedrine Sulfate tablets*.

**NATURE OF CHARGE:** While a number of the *Ergoapiol with Savin capsules* were being held for sale at the Jack Clayton Drug Store after shipment in interstate commerce, Leroy M. Clayton, on or about September 30, 1949, and Paul E. Calmes and Leroy M. Clayton, on or about October 3, 1949, caused the capsules to be sold and disposed of to two different purchasers in the original bottles in which the capsules had been shipped in interstate commerce, without requiring a prescription of a physician. When received by the defendant, the label of the capsules bore the statement "Caution—To be dispensed only by or on the prescription of a physician," and as a result the capsules were not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling. However, by selling the capsules without a prescription, the defendants caused the exemption to expire, resulting in the misbranding of the capsules, in violation of Section 502 (f) (1), since the bottles bore no labeling containing directions for use.

In addition to the above sales, defendant Clayton, on or about September 27 and 28 and October 3 and 4, 1949, caused various quantities of *sulfadiazine tablets*, *Seconal Sodium capsules*, and *Dewedrine Sulfate tablets* to be repackaged and sold without a prescription while they were being held for sale at the Jack Clayton Drug Store after shipment in interstate commerce, which acts resulted in the repackaged drugs being misbranded as follows: Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements setting forth the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a derivative of barbituric acid, which derivative has been designated by regulations as habit forming; and when repackaged, the capsules bore no labeling containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* and *Dewedrine Sulfate tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

**DISPOSITION:** June 12, 1950. Pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of \$200 against defendant Clayton and \$25 against defendant Calmes.

**3168. Misbranding of sulfadiazine tablets and apiol and ergotin compound capsules.** U. S. v. Stone's Pharmacy, Joseph H. Stone, and Leon Stone. Pleas of nolo contendere. Fine of \$200 against pharmacy and \$100 against each individual; in addition, pharmacy placed on probation for 2 years and each individual for 1 year. (F. D. C. No. 28135. Sample Nos. 55336-K, 55338-K.)

**INFORMATION FILED:** April 25, 1950, District of Nebraska, against Stone's Pharmacy, a partnership, North Platte, Nebr., and against Joseph H. Stone and Leon Stone, partners in the partnership.

**INTERSTATE SHIPMENT:** From the States of New York and Missouri into the State of Nebraska, of quantities of *sulfadiazine tablets* and *apiol and ergotin compound capsules*.