

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*.

ALLEGED VIOLATION: On or about June 14 and 16, 1949, while a number of the above-mentioned tablets and capsules were being held for sale at Stone's Pharmacy after shipment in interstate commerce, various quantities of the tablets and capsules were repacked and sold without a prescription, which acts resulted in the repackaged tablets and capsules being misbranded.

Stone's Pharmacy was charged with causing the acts of repacking and sale of the drugs involved in each of the two counts of the information; and, in addition, Joseph H. Stone, in one of the counts, and Leon Stone, in the other count, 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), the repackaged *sulfadiazine tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged *sulfadiazine tablets* and *apiol and ergotin compound capsules* failed to bear labels containing statements of the quantity of the contents; and, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the drug.

Further misbranding, Section 502 (e) (2), the repackaged *apiol and ergotin compound capsules* failed to bear a label containing the common or usual name of each active ingredient since each capsule contained, in addition to *apiol* and *ergotin*, the active ingredient, *aloin*; and the label of the repackaged capsules failed to bear the common or usual name of the active ingredient, *aloin*.

Further misbranding, Section 502 (f) (1), the repackaged tablets and capsules bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine 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 27, 1950. Pleas of *nolo contendere* having been entered, the court imposed a fine of \$200 against the pharmacy and \$100 against each individual, plus costs, and placed the pharmacy on probation for a period of 2 years and each individual for a period of 1 year.

3169. Misbranding of *apiol* and *ergot* compound capsules. U. S. v. Davis Drug Co. and Wilford S. Nelson. Pleas of *nolo contendere*. Each defendant fined \$100, plus costs, and placed on probation for 1 year. (F. D. C. No. 28134. Sample No. 55457-K.)

INFORMATION FILED: April 25, 1950, District of Nebraska, against the Davis Drug Co., a partnership, North Platte, Nebr., and Wilford S. Nelson, a pharmacist for the partnership.

INTERSTATE SHIPMENT: On or about January 25, 1949, from the State of Indiana into the State of Nebraska.

ALLEGED VIOLATION: On or about June 16, 1949, while the capsules were being held for sale after shipment in interstate commerce, the defendants caused a number of the capsules to be removed from the bottle in which they had been shipped and to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged capsules failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.