

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

3464. Misbranding of Seconal Sodium capsules, Carbrital capsules, and pentobarbital sodium capsules. U. S. v. Corner Drug Co., Inc. (Donovan Drug Co.), and Charles E. Donovan. Pleas of nolo contendere. Fine of \$250 against corporation and \$50 against individual. (F. D. C. No. 30570. Sample Nos. 80018-K to 80020-K, incl., 80282-K, 80285-K, 80296-K, 80297-K, 80301-K, 80310-K, 80318-K, 80319-K, 80359-K.)

INFORMATION FILED: June 1, 1951, District of Massachusetts, against Corner Drug Co., Inc., trading as the Donovan Drug Co., Boston, Mass., and against Charles E. Donovan, treasurer of the corporation.

INTERSTATE SHIPMENT: From the States of Indiana, Michigan, and New York, into the State of Massachusetts, of quantities of *Second Sodium capsules*, *Carbrital capsules*, and *pentobarbital sodium capsules*.

ALLEGED VIOLATION: On or about September 1, 5, 6, 8, 11, 13, 16, 18, and 20, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents. Further misbranding, Section 502 (d), the repackaged capsules contained chemical derivatives of barbituric acid, which derivatives have 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"; and, in addition, the *Carbrital capsules* contained a substance, carbromal, and the label of the capsules failed to bear the name, and quantity or proportion of such substance and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since the directions "One at bed time" appearing in the labeling of the *Seconal Sodium capsules*, "One capsule at bed time" appearing in the labeling of the *Carbrital capsules*, and "One capsule at night" and "One at night" appearing in the labeling of a number of the repackaged *pentobarbital sodium capsules* were not adequate directions for use, and since the labeling of a portion of the repackaged *pentobarbital sodium capsules* bore no directions for use.

DISPOSITION: June 12, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$250 against the corporation and \$50 against the individual.

3465. Misbranding of Seconal Sodium capsules and Benzedrine Sulfate tablets. U. S. v. Robert L. Mealy (Mason Pharmacy). Plea of guilty. Fine, \$300. (F. D. C. No. 29451. Sample Nos. 60670-K to 60672-K, incl., 60674-K.)

INFORMATION FILED: September 6, 1950, Eastern District of Wisconsin, against Robert L. Mealy, trading as the Mason Pharmacy, Milwaukee, Wis.

ALLEGED SHIPMENT: From the States of Indiana and Pennsylvania into the State of Wisconsin, of quantities of *Seconal Sodium capsules* and *Benzedrine Sulfate tablets*.