

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

3301. Misbranding of Seconal Sodium capsules. U. S. v. Jones Drug Co. and Walter W. Hafley. Pleas of guilty. Fine of \$20 against each defendant. (F. D. C. No. 29478. Sample Nos. 31933-K, 31935-K, 58077-K, 58152-K.)

INFORMATION FILED: November 1, 1950, District of Arizona, against the Jones Drug Co., a partnership, Tucson, Ariz., and Walter W. Hafley, a partner in the partnership.

INTERSTATE SHIPMENT: Between the approximate dates of April 14 and June 15, 1949, from the State of Indiana into the State of Arizona.

ALLEGED VIOLATION: On or about July 20 and August 12, 23, and 25, 1949, while the drug was held for sale after shipment in interstate commerce, the defendant caused a number of the *Seconal Sodium capsules* to be repacked and sold without a prescription, which acts resulted in the capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label 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 directions for use "One capsule at bedtime," borne on the labeling of the repackaged capsules, were not adequate directions for use.

DISPOSITION: November 15, 1950. Pleas of guilty having been entered, the court imposed a fine of \$20 against each defendant.

3302. Misbranding of Seconal Sodium capsules and Benzedrine Sulfate tablets. U. S. v. Joseph P. Piszczek (Piszczek's Pharmacy). Plea of guilty. Fine \$300. (F. D. C. No. 29445. Sample Nos. 15846-K to 15849-K, incl.)

INFORMATION FILED: September 6, 1950, Eastern District of Wisconsin, against Joseph P. Piszczek, trading as Piszczek's Pharmacy, Milwaukee, Wis.

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

ALLEGED VIOLATION: On or about October 7, 10, 13, and 17, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the *Seconal Sodium capsules* and the *Benzedrine Sulfate tablets* to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing a statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use; and Section 502 (b) (1), a portion of the repackaged *Seconal Sodium capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations