

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

3945. Misbranding of pentobarbital sodium capsules. U. S. v. Duvall Pharmacy, Inc., and Charles H. Wagner. Pleas of guilty. Fine of \$300 against each defendant, plus costs. (F. D. C. No. 33740. Sample Nos. 3995-L, 3996-L, 4009-L.)

INFORMATION FILED: January 23, 1953, District of Maryland, against Duvall Pharmacy, Inc., Baltimore, Md., and Charles H. Wagner, vice president and pharmacist for the corporation.

ALLEGED VIOLATION: On or about November 7 and 13 and December 4, 1951, while a number of *pentobarbital sodium capsules* were being held for sale at Duvall Pharmacy, Inc., after shipment in interstate commerce, the defendants caused various quantities of the capsules to be repacked and dispensed without a prescription, which acts resulted in the repackaged capsules being misbranded.

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

Further misbranding, Section 502 (d), the repackaged capsules contained a chemical derivative of barbituric acid, which derivative has been 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 labeling of the repackaged capsules failed to bear adequate directions for use.

DISPOSITION: February 27, 1953. Pleas of guilty having been entered on behalf of the defendants, the court fined each defendant \$300, plus costs.

3946. Misbranding of Seconal Sodium capsules. U. S. v. L & S Pharmacy, Inc. (Whelan Drug (Sales Agency)), Stephan Stimac, and James M. Loureiro. Pleas of nolo contendere. Fine of \$200 against each defendant. (F. D. C. No. 33755. Sample Nos. 26899-L to 26902-L, incl., 27586-L to 27588-L, incl.)

INFORMATION FILED: February 26, 1953, Northern District of California, against L & S Pharmacy, Inc., doing business as Whelan Drug (Sales Agency), and against Stephan Stimac, president of the corporation, and James M. Loureiro, secretary-treasurer.

ALLEGED VIOLATION: On or about November 21, 23, 26, and 29, and December 4, 5, 6, and 18, 1951, while a number of *Seconal Sodium capsules* were being held for sale at L & S Pharmacy, Inc., after shipment in interstate commerce, the defendants caused various quantities of the *Seconal Sodium capsules* to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged capsules being misbranded.

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

*See also Nos. 3941, 3943.

Further misbranding, Section 502 (d), the repackaged capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the 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 labeling of the repackaged capsules failed to bear adequate directions for use.

DISPOSITION: March 30, 1953. Pleas of nolo contendere having been entered by the defendants, the court fined each defendant \$200.

3947. Misbranding of Seconal Sodium capsules and amphetamine sulfate tablets. U. S. v. John L. Tarlow (Tarlow Drug). Plea of guilty. Fine, \$500. (F. D. C. No. 33800. Sample Nos. 6580-L, 6581-L, 6583-L.)

INFORMATION FILED: February 5, 1953, District of Massachusetts, against John L. Tarlow, trading as Tarlow Drug, at Boston, Mass.

ALLEGED VIOLATION: On or about March 25 and 26, 1952, while a number of *Seconal Sodium capsules* and *amphetamine sulfate tablets* were being held for sale, after shipment in interstate commerce, the defendant caused quantities of the drugs to be dispensed without a physician's prescription, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the dispensed drugs failed to bear adequate directions for use; and, Sections 502 (b) (1) and (2), the *amphetamine sulfate tablets* and a portion of the *Seconal Sodium capsules* were in package form and failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Seconal 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 capsules failed to bear a label 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 (e) (1), the *amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the *amphetamine sulfate tablets* failed to bear adequate 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, in such manner and form, as are necessary for the protection of users.

DISPOSITION: February 25, 1953. A plea of guilty having been entered, the court fined the defendant \$500.

3948. Misbranding of amphetamine sulfate tablets. U. S. v. Hy-Gold Drug Co., Inc., and Boris Golden. Pleas of nolo contendere. Fine of \$200 against corporation and \$100 against individual. (F. D. C. No. 33845. Sample Nos. 33542-L, 33546-L, 33554-L, 33567-L.)

INFORMATION FILED: December 16, 1952, Northern District of Illinois, against Hy-Gold Drug Co., Inc., Chicago., Ill., and Boris Golden, manager and secretary-treasurer of the corporation.

ALLEGED VIOLATION: On or about October 9, 15, 19, and 30, 1951, while a number of *amphetamine sulfate tablets* were being held for sale at the Hy-Gold Drug