

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

**DRUGS FOR HUMAN USE**

**3386. Misbranding of pentobarbital sodium capsules. U. S. v. Bunting & Son, Inc. Plea of guilty. Fine, \$800. (F. D. C. No. 29460. Sample Nos. 2936-K to 2939-K, incl.)**

**INFORMATION FILED:** October 17, 1950, Eastern District of Tennessee, against Bunting & Son, Inc., Bristol, Tenn.

**INTERSTATE SHIPMENT:** From the States of Ohio and Illinois into the State of Tennessee, of quantities of *pentobarbital sodium capsules*.

**ALLEGED VIOLATION:** On or about August 8, 11, 15, and 22, 1949, while the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules to be repackaged 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 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, in that the directions "One capsule at bedtime as needed for rest," borne on the labeling, were not adequate directions for use.

**DISPOSITION:** March 5, 1951. A plea of guilty having been entered, the court imposed a fine of \$800 against the defendant.

**3387. Misbranding of phenobarbital tablets. U. S. v. Nicholas Paris (Paris Drug Store). Plea of nolo contendere. Defendant fined \$500 and placed on probation for 1 year. (F. D. C. No. 29993. Sample Nos. 49741-K, 49743-K, 75194-K.)**

**INFORMATION FILED:** December 20, 1950, District of Colorado, against Nicholas Paris, trading as the Paris Drug Store, Denver, Colo.

**INTERSTATE SHIPMENT:** On or about February 28, 1950, from the State of Missouri into the State of Colorado, of a quantity of *phenobarbital tablets*.

**ALLEGED VIOLATION:** On or about April 3, 6, and 10, 1950, while the tablets were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the tablets to be repackaged and sold without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

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

Further misbranding, Section 502 (d), the tablets 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 tablets failed to bear the name, and quantity or proportion of such derivative