

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

3761. Misbranding of sulfathiazole tablets. U. S. v. Hugh Allen (Hugh Allen, Druggist). Plea of guilty. Imposition of sentence suspended and defendant placed on probation for 6 months. (F. D. C. No. 31562. Sample Nos. 3180-L, 3181-L.)

INFORMATION FILED: April 21, 1952, Northern District of West Virginia, against Hugh Allen, trading as Hugh Allen, Druggist, Petersburg, W. Va.

INTERSTATE SHIPMENT: From the State of Indiana into the State of West Virginia of quantities of *sulfathiazole tablets*.

ALLEGED VIOLATION: On or about May 10 and 15, 1951, while a number of tablets of the drug were being held for sale after shipment in interstate commerce, the defendant caused a number of such tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged drug was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the repackaged drug; and, Sections 502 (f) (1) and (2), the labeling of the repackaged drug failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 15, 1952. A plea of guilty having been entered, the court suspended the imposition of sentence and placed the defendant on probation for 6 months.

3762. Misbranding of Seconal Sodium capsules. U. S. v. Andrew Kolanowski. Plea of guilty. Fine, \$100. (F. D. C. No. 32746. Sample No. 9420-L.)

INFORMATION FILED: April 25, 1952, Northern District of Illinois, against Andrew Kolanowski, an assistant pharmacist for Marshall Drugs, Chicago, Ill.

ALLEGED VIOLATION: On or about April 5, 1951, while a number of *Seconal Sodium capsules* were being held for sale at Marshall Drugs, after shipment in interstate commerce, the defendant caused a number of the capsules to be repacked and dispensed without a physician's prescription, which acts resulted in the drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear a label 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 repackaged drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged drug 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."