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

2971. Misbranding of sulfathiazole lozenges and Hexital tablets. U. S. v. Joe Gailey (McGreevy Drug Co., No. 1). Plea of guilty. Fine, $50. (F. D. C. No. 26713. Sample Nos. 27032–K, 27042–K.)

INFORMATION FILED: June 29, 1949, Western District of Missouri, against Joe Gailey, a partner in the partnership of McGreevy Drug Co., No. 1, Springfield, Mo.

INTERSTATE SHIPMENT: On or about January 30, 1948, from Indianapolis, Ind., of a quantity of *sulfathiazole lozenges*, and between the approximate dates of January 16, 1947, and September 20, 1948, from Raritan, N. J., of a quantity of *Hexital tablets*.

LABEL, WHEN SHIPPED: (Sulfathiazole lozenges) "Lozenges Sulfathiazole * * * 5 grs."; (Hexital tablets) "Each Tablet Contains Phenobarbital 20 Mg. * * * Hexestrol—3 Mg. Hexital." (Both products) "Caution: To Be Dispensed Only By Or On the Prescription of a Physician."

ALLEGED VIOLATION: On or about August 13 and September 20, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of *sulfathiazole lozenges* and *Hexital tablets* to be removed from the bottles in which they had been shipped, to be repacked, and to be sold to an individual without a prescription, which acts of the defendant resulted in the lozenges and tablets being misbranded. The repackaged drugs were labeled "Sulfathiazole Lozenges McGreevy Drug Co. * * * Springfield, Mo." and "Hexital McGreevy No. 1, Springfield, Mo."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the label borne on the containers of the repackaged drugs contained no statement of the quantity of the contents; Section 502 (f) (1), the containers of the repackaged drugs bore no labeling containing directions for use; and, Section 502 (e) (2), the repackaged *Hexital tablets* were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and the label borne on the repackaged tablets failed to bear the common or usual name of each active ingredient, namely, "phenobarbital" and "hexestrol."

Further misbranding, Section 502 (d), the repackaged *Hexital tablets* were a drug for use by man and contained a chemical derivative of barbituric acid, namely, "phenobarbital," which derivative had been by the Administrator of the Federal Security Agency, after investigation, 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 and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the repackaged *sulfathiazole lozenges* bore no labeling containing warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: November 18, 1949. A plea of guilty having been entered, the court imposed a fine of $50.

2972. Misbranding of seconal sodium capsules and amphetamine phosphate tablets. U. S. v. George R. Murchison (Murchison's Pharmacy). Plea