

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

3241. Misbranding of sulfathiazole lozenges, Dexedrine Sulfate tablets, and Tuinal capsules. U S. v. Elias A. Doerr (Doerr's Drug Store), and Arthur R. Morgan. Pleas of guilty. Each defendant fined \$100 and placed on probation for 1 year. (F. D. C. No. 28121. Sample Nos. 61307-K, 61312-K, 61315-K, 61316-K.)

INFORMATION FILED: January 31, 1950, Eastern District of Illinois, against Elias A. Doerr, trading as Doerr's Drug Store, Murphysboro, Ill., and Arthur R. Morgan, a pharmacist.

INTERSTATE SHIPMENT: On or about December 10, 1947, and April 21 and May 27, 1949, from the States of Indiana and Missouri into the State of Illinois, of quantities of *sulfathiazole lozenges*, *Dexedrine Sulfate tablets*, and *Tuinal capsules*.

ALLEGED VIOLATION: On or about July 22 and 27, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants, Elias A. Doerr and Arthur R. Morgan, caused a number of *sulfathiazole lozenges* and a number of *Dexedrine Sulfate tablets* to be repackaged and sold without a prescription, and on July 28, 1949, defendant Elias A. Doerr caused a number of *sulfathiazole lozenges* and a number of *Tuinal capsules* to be repackaged and sold without a prescription, which acts of the defendants resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), one sale of the repackaged *sulfathiazole lozenges* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Tuinal capsules* contained derivatives of barbituric acid, which derivatives had been found to be, and by regulations designated as, habit forming; and when repackaged, the *Tuinal capsules* failed to bear a label containing the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), all of the repackaged drugs failed to bear labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfathiazole lozenges* bore no labeling containing 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.

DISPOSITION: September 25, 1950. Pleas of guilty having been entered, the court fined each defendant \$100 and placed each on probation for 1 year.

3242. Misbranding of sulfathiazole tablets. U. S. v. Stephen S. Titus (Titus Pharmacy). Plea of guilty. Fine, \$600. (F. D. C. No. 29415. Sample Nos. 13614-K, 13619-K, 13805-K.)

INFORMATION FILED: June 29, 1950, Eastern District of Pennsylvania, against Stephen S. Titus, trading as Titus Pharmacy, Philadelphia, Pa.

INTERSTATE SHIPMENT: On or about September 10, 1948, from the State of New York into the State of Pennsylvania, of a quantity of *sulfathiazole tablets*.

ALLEGED VIOLATION: On or about July 15 and August 2 and 10, 1949, while a number of the *sulfathiazole tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a prescription, which acts resulted in the tablets being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets 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; and Section 502 (e) (1), the label of the repackaged tablets failed to bear the common or usual name of the drug, namely, sulfathiazole.

Further misbranding, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use since the labeling of the tablets involved in one of the sales bore no directions for use and since the directions, "2-1/4 x a day" and "2-1 Every 4 hours," borne on the labeling of the tablets involved in the other sales, were not adequate directions for use; and, Section 502 (f) (2), the labeling of the repackaged tablets bore no 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.

DISPOSITION: October 9, 1950. A plea of guilty having been entered, the court imposed a fine of \$600.

3243. Misbranding of sulfathiazole tablets. U. S. v. Jacob Sheckter (Sheckter's Drug Store). Plea of guilty. Fine, \$300. (F. D. C. No. 29128. Sample Nos. 13820-K, 48547-K, 48655-K.)

INFORMATION FILED: June 29, 1950, Eastern District of Pennsylvania, against Jacob Sheckter, trading as Sheckter's Drug Store, Philadelphia, Pa.

INTERSTATE SHIPMENT: Between the approximate dates of May 31 and September 28, 1949, from the State of Maryland into the State of Pennsylvania.

ALLEGED VIOLATION: On or about October 24 and 28 and November 3, 1949, while the *sulfathiazole tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets 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; and Section 502 (e) (1), the label of the repackaged tablets failed to bear the common or usual name of the drug, namely, sulfathiazole.

Further misbranding, Section 502 (f) (1), the repackaged *sulfathiazole tablets* failed to bear labeling containing adequate directions for use; and, Section 502 (f) (2), the tablets bore no labeling containing 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.

DISPOSITION: October 2, 1950. A plea of guilty having been entered, the court imposed a fine of \$300.