NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "1 teaspoonful every 3 or 4 hours," since administration of 1 teaspoonful every 3 or 4 hours is capable of causing leucopenia.

The article also was in violation of Section 505 (a) since it was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: November 14, 1949. Marvin R. Thompson, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Federal Security Agency.

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

2853. Misbranding of benadryl capsules, Dexedrine sulfate tablets, sulfathiazole lozenges, and nembutal and aspirin capsules. U. S. v. Charles E. Prescott (Prescott Drug Store). Plea of nolo contendere. Fine, $1,000. (F. D. C. No. 26718. Sample Nos. 27056-K, 45894-K, 46419-K, 46422-K.)

INFORMATION FILED: July 8, 1949, Western District of Tennessee, against Charles E. Prescott, trading as the Prescott Drug Store, Memphis, Tenn.

INTERSTATE SHIPMENT: Between the approximate dates of February 17 and December 8, 1948, of one lot of *benadryl capsules*, from St. Louis, Mo.; one lot of *Dexedrine sulfate tablets*, from Philadelphia, Pa.; 1 lot of *sulfathiazole lozenges*, from Indianapolis, Ind.; and 1 lot of *nembutal and aspirin capsules*, from Chicago, Ill.

ALLEGED VIOLATION: On or about January 14, 15, 17, and 18, 1949, and while the articles were being held for sale after shipment in interstate commerce, the defendant caused quantities of the articles to be removed from the bottles in which they had been shipped, and repacked and sold them to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded. When shipped in interstate commerce, the articles bore on their labels the prescription legend prescribed by the regulations. The quantities of the articles which were repacked and sold by the defendant were labeled, "Benadryl Capsules 50 Mg. [or "Sulfathiazole Lozenges" or "Nembutal & Aspirin"] Prescott Drugs, Memphis Tennessee" and "Dexedrine Sulfate Tablets."

NATURE OF CHARGE: Misbranding Section 502 (b) (2), the repackaged articles bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), they failed to bear labeling containing adequate directions for use.

Further misbranding, Section 502 (b) (1), the *Dexedrine sulfate tablets* bore no label containing the name and place of business of the manufacturer, packer, or distributor. Section 502 (d), the *nembutal and aspirin tablets* were a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be, and by regulations designated as, habit-forming; and the labels of the repackaged *nembutal and aspirin capsules* failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement, "Warning—May be habit forming";

and, 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: July 22, 1949. A plea of nolo contendere having been entered, the court imposed a fine of $1,000.

2854. Misbranding of seconal sodium capsules, phenobarbital tablets, amytal tablets, Dexedrine sulfate tablets, and diethylstilbestrol tablets. U. S. v. Kay Surgical, Inc., and Thomas M. Wardlaw. Pleas of nolo contendere. Fine of $1,000 against corporation and $250 against individual. (F. D. C. No. 26714. Sample Nos. 27054–K, 27059–K, 46417–K, 46418–K, 46423–K to 46425–K, incl.)

INFORMATION FILED: July 8, 1949, Western District of Tennessee, against Kay Surgical, Inc., and Thomas M. Wardlaw, a pharmacist for the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of December 29, 1947, and December 28, 1948, from Indianapolis, Ind., and Philadelphia, Pa., of 3 lots of *seconal sodium capsules*, 1 lot of *phenobarbital tablets*, 1 lot of *amytal tablets*, 1 lot of *Dexedrine sulfate tablets*, and 1 lot of *diethylstilbestrol tablets*.

ALLEGED VIOLATION: On or about January 14, 15, 17, and 19, 1949, and while the articles were being held for sale after shipment in interstate commerce, the defendants caused quantities of the articles to be removed from the bottles in which they had been shipped, and repacked and sold them to various persons without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. When shipped in interstate commerce, the articles had borne on their labels the prescription legend prescribed by the regulations. With the exception of one lot of *seconal sodium capsules*, the repackaged drugs were labeled, in part: "Kay Surgical, Inc. * * * Memphis, Tenn. Seconal Capsules [or "Amytal Tablets 1½ grs.," "Stilbesteral 1 mg.," "Phenobarbital 1½ grains," or "Dexedrine"]." One lot of the repackaged *seconal sodium capsules* was labeled, in part: "Kay Surgical, Inc. * * * Memphis, Tenn. 58975 1–14–49 Take one when needed Dr. Pearce."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged articles bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged articles failed to bear labeling containing adequate directions for use.

Further misbranding, Section 502 (d), the *seconal sodium capsules*, the *amytal tablets*, and the *phenobarbital tablets* were drugs for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be, and by regulations designated as, habit-forming; and the labels of the repackaged *seconal sodium capsules* the *amytal tablets*, and the *phenobarbital tablets* failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement, "Warning—May be habit forming"; and, Section 502 (e) (1), the label on one lot of the repackaged *seconal sodium capsules* failed to bear the common or usual name of the drug.

DISPOSITION: July 22, 1949. Pleas of nolo contendere having been entered, the court imposed a fine of $1,000 against the corporation and a fine of $250 against the individual.