

NATURE OF CHARGE: On or about July 14, 17, 18, 21, and 22, 1952, while quantities of *Tuinal capsules*, *Secobarbital Sodium capsules*, *racemic amphetamine sulfate tablets*, *pentobarbital sodium capsules*, and *methyltestosterone linguets* were being held for sale at Highland Pharmacies, Inc., Store No. 2, after shipment in interstate commerce, the defendants caused various quantities of the drugs to be dispensed without prescriptions from practitioners licensed by law to administer such drugs. This dispensing was contrary to Section 503 (b) (1) and resulted in the drugs so dispensed being misbranded while held for sale.

DISPOSITION: November 14, 1952. A plea of *nolo contendere* having been entered on behalf of the corporation and a plea of guilty on behalf of the individual defendant, the court imposed a fine of \$750 against the corporation and sentenced the individual to 90 days in prison.

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

3863. Misbranding of phenobarbital tablets, dextro-amphetamine sulfate tablets, sulfadiazine tablets, and diethylstilbestrol tablets. *U. S. v. John E. Stephens (John E. Stephens Drugs)*, and Andrew J. Collinsworth. Pleas of *nolo contendere*. John E. Stephens fined \$2,000 and Andrew J. Collinsworth \$500. (F. D. C. No. 31264. Sample Nos. 31371-L, 31373-L, 31915-L, 31916-L, 31923-L, 31924-L, 31926-L, 31927-L.)

INFORMATION FILED: December 6, 1951, Western District of Tennessee, against John E. Stephens, trading as John E. Stephens Drugs, at Memphis, Tenn., and Andrew J. Collinsworth, pharmacist.

INTERSTATE SHIPMENT: From the States of Pennsylvania and Indiana into the State of Tennessee, of quantities of *phenobarbital tablets*, *dextro-amphetamine sulfate tablets*, *sulfadiazine tablets*, and *diethylstilbestrol tablets*.

ALLEGED VIOLATION: On or about February 20 and 23, April 28 and 29, and May 6, 10, and 11, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

John E. Stephens, as owner, was made a defendant in all counts; and, in addition, Andrew J. Collinsworth, the pharmacist, was joined as a defendant in three of the counts involving sales made by him.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* 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."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no warning against use in those pathological con-

*See also No. 3878 (veterinary preparation).

ditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: December 14, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$2,000 against John E. Stephens and \$500 against Andrew J. Collinsworth.

3864. Misbranding of inositol hexanitate and phenobarbital tablets, thyroid tablets, dextro-amphetamine sulfate tablets, and sulfadiazine tablets. U. S. v. Joseph K. Carlisle (Carlisle Drug Store). Plea of guilty. Fine of \$500, plus costs. (F. D. C. No. 33729. Sample Nos. 34340-L, 34347-L, 34348-L, 34354-L, 34355-L, 34453-L.)

INFORMATION FILED: November 20, 1952, Southern District of Illinois, against Joseph K. Carlisle, trading as Carlisle Drug Store, Chillicothe, Ill.

ALLEGED VIOLATION: On or about February 20, 25, and 28, and March 3, 1952, while quantities of *inositol hexanitate and phenobarbital tablets, thyroid tablets, dextro-amphetamine sulfate tablets, and sulfadiazine tablets* were being held for sale at the Carlisle Drug Store after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *inositol hexanitate and phenobarbital 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 such repackaged drug 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 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the repackaged *inositol hexanitate and phenobarbital tablets* and *dextro-amphetamine sulfate tablets* were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* failed to bear labeling containing adequate 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, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 3, 1952. A plea of guilty having been entered, the court imposed a fine of \$500, plus costs.

3865. Misbranding of Combisul-DM tablets, dextro-amphetamine sulfate tablets, and pentobarbital sodium capsules. U. S. v. Irving L. Rutkoff (Fayetteville Pharmacy). Plea of guilty. Fine, \$104. (F. D. C. No. 31298. Sample Nos. 74167-K, 74169-K, 74171-K, 74174-K, 74176-K.)

INFORMATION FILED: May 15, 1952, Northern District of New York, against Irving L. Rutkoff, trading as the Fayetteville Pharmacy, Fayetteville, N. Y.

ALLEGED VIOLATION: On or about October 30 and November 1, 8, and 27, 1950, while quantities of *Combisul-DM tablets, dextro-amphetamine sulfate tablets,*