amphetamine sulfate tablets, and *capsules containing a mixture of pentobarbital and aspirin* were being held for sale at the Steele Drug Co., 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, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels 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 (f) (1), the repackaged drugs failed to bear labeling containing adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *capsules containing a mixture of pentobarbital and aspirin* contained a chemical derivative of barbituric acid, namely, pentobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the labeling of the repackaged capsules 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) (2), a portion of the *methyltestosterone tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug; and, Section 502 (f) (2), the repackaged *methamphetamine hydrochloride 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 22, 1952. A plea of nolo contendere having been entered by the defendant, the court fined him $350.

4009. Misbranding of sulfathiazole tablets. U. S. v. Manion Mitchell (Gilbert Drug Co.), and Harry E. Mitchell. Pleas of guilty. Fine of $50 against each defendant. (F. D. C. No. 33854. Sample Nos. 20904–L, 22169–L, 22198–L, 22210–L.)

INFORMATION FILED: February 17, 1953, Northern District of Alabama, against Manion Mitchell, trading as the Gilbert Drug Co., Athens, Ala., and Harry E. Mitchell, a pharmacist.

ALLEGED SHIPMENT: On or about November 7 and December 20, 1951, and January 10 and 11, 1952, while a number of *sulfathiazole tablets* were being held for sale at the Gilbert Drug Co., after shipment in interstate commerce, the defendants caused various quantities of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label containing the common or usual name of the drug; and, Sections 502 (f) (1) and (2), the labeling of the repackaged tablets failed to bear adequate directions for use and 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: April 7, 1953. Pleas of guilty having been entered by the defendants, the court fined each defendant $50.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4010. Adulteration and misbranding of amphetamine sulfate tablets. U. S. v. 11 Bottles * * *. (F. D. C. No. 31380. Sample No. 11171–L.)

LIBEL FILED: July 23, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about the first quarter of 1950 by the International Pharmaceutical Laboratories, from Great Neck, N. Y.

PRODUCT: 11 unlabeled 1,000-tablet bottles of *amphetamine sulfate tablets*. Examination showed that each tablet contained not more than 8.6 milligrams of amphetamine sulfate. The product was represented by a representative of the shipper to be 10-milligram amphetamine sulfate tablets.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, namely, 8.6-milligram *amphetamine sulfate tablets*, had been substituted for 10-milligram amphetamine sulfate tablets.

Misbranding, Sections 502 (b) (1) and (2), the article 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 article failed to bear the common or usual name of the article, namely, "*amphetamine sulfate tablets*."

DISPOSITION: The Lipton Drug Sales Co., Cleveland, Ohio, claimant, filed an answer admitting that the drug was shipped unlabeled but denying that the drug was adulterated and misbranded, together with a set of interrogatories to be answered by the Government.

After the Government answered the interrogatories, it filed a motion for summary judgment. On November 20, 1951, the court granted the Government's motion, on the ground that there was no genuine issue on the material fact that the product was transported from New York to Ohio without being labeled and was therefore subject to seizure as a misbranded drug. On January 21, 1952, a decree was entered providing for the condemnation and destruction of the product.

4011. Adulteration of sulfadiazine tablets. U. S. v. 13 Bottles * * *. (F. D. C. No. 33275. Sample No. 37685–L.)

LIBEL FILED: June 3, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about May 7, 1952, by the Berkeley Drug Co., from Boston, Mass.

PRODUCT: 13 1,000-tablet bottles of *sulfadiazine tablets* at Brooklyn, N. Y.

LABEL, IN PART: (Bottle) "1000 Sulfadiazine * * * (2-Sulfanilamidopyrimidine) Compressed Tablets (scored) 0.5 Gm. (7.7 Grains)."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sulfadiazine Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard. The standard provides that sulfadiazine tablets contain not less than 95 percent of the labeled amount of sulfadiazine, whereas the article contained not more than 77 percent of the labeled amount of sulfadiazine.

DISPOSITION: May 26, 1953. Default decree of condemnation and destruction.