

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

4141. Misbranding of Seconal Sodium capsules, amphetamine hydrochloride tablets, dextro-amphetamine sulfate tablets, and pentobarbital sodium capsules. U. S. v. Charles J. Bridgman (Bridgman Drug), and Otto A. Greiser. Pleas of nolo contendere. Defendant Bridgman fined \$900 and Defendant Greiser placed on probation for 6 months. (F. D. C. No. 33726. Sample Nos. 35050-L, 35054-L, 35414-L, 35415-L, 35422-L, 35423-L.)

INFORMATION FILED: May 4, 1953, Southern District of Iowa, against Charles J. Bridgman, trading as Bridgman Drug, Des Moines, Iowa, and against Otto A. Greiser, an employee of Mr. Bridgman.

ALLEGED VIOLATION: On or about November 19 and 26 and December 4 and 5, 1951, while a number of *Seconal Sodium capsules, amphetamine hydrochloride tablets, dextro-amphetamine sulfate tablets, and pentobarbital sodium capsules* were being held for sale at Bridgman Drug, after shipment in interstate commerce, the defendants caused various quantities of such 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) (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 labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* and *pentobarbital sodium capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and such repackaged drugs failed to bear labels containing the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the labels of the repackaged *amphetamine hydrochloride tablets* and *dextro-amphetamine sulfate tablets* failed to bear the common or usual name of each active ingredient of such drugs; and, Section 502 (f) (2), the labeling of the repackaged *amphetamine hydrochloride tablets* failed to bear 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: May 4, 1953. The defendants having entered pleas of nolo contendere, the court fined Defendant Bridgman \$900 and placed Defendant Greiser on probation for 6 months.

4142. Misbranding of methyltestosterone tablets, phenobarbital tablets, and amphetamine sulfate tablets. U. S. v. Goldberg Drug Store, Edward J. Rubas, and John Tarczewski. Pleas of guilty. Fine of \$500 against store and fine of \$250 against each individual, plus costs. (F. D. C. No. 33843. Sample Nos. 9448-L, 33531-L, 33537-L to 33539-L, incl., 33543-L to 33545-L, incl.)

*See also No. 4157 (veterinary preparation).

INFORMATION FILED: February 18, 1953, Northern District of Illinois, against Goldberg Drug Store, a partnership, Chicago, Ill., and against Edward J. Rubas, an employee, and John Tarczewski, a pharmacist for the store.

ALLEGED VIOLATION: On or about October 6, 12, and 27, 1951, while quantities of *methyltestosterone tablets*, *phenobarbital tablets*, and *amphetamine sulfate tablets* were being held for sale at the Goldberg Drug Store, after shipment in interstate commerce, various quantities of such drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded; and, on or about October 3 and 12, 1951, while a number of *methyltestosterone tablets* were being held for sale at the Goldberg Drug Store, after shipment in interstate commerce, 3 bottles of such tablets were dispensed in the original bottles in which the tablets had been shipped in interstate commerce, without the prescription of a physician, which acts resulted in the tablets being misbranded. The partnership and Edward J. Rubas were charged with causing the acts of dispensing with respect to the *amphetamine sulfate tablets*, and the partnership and John Tarczewski were charged with causing the acts of dispensing with respect to the other drugs involved.

NATURE OF CHARGE: *Methyltestosterone tablets* (dispensed in original bottles). Misbranding, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use. (The bottles in which the tablets were shipped in interstate commerce did not bear adequate directions for use since they were exempt from such requirement by the label statement "Caution: To be dispensed only by or on the prescription of a physician." The act of dispensing the tablets without a physician's prescription, however, caused the exemption to expire.)

Phenobarbital tablets, *amphetamine sulfate tablets*, and *methyltestosterone tablets* (repackaged). Misbranding, Section 502 (b) (1) and (2), the 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 labeling of the 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 label of the 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 (e) (1), the *methyltestosterone tablets* and *amphetamine sulfate tablets* failed to bear labels containing the common or usual name of the drug.

DISPOSITION: June 12, 1953. The defendants having entered pleas of guilty, the court fined the partnership \$500 and each individual \$250, plus costs.

4143. Misbranding of dextro-amphetamine sulfate tablets, conjugated estrogens (equine) tablets, methyltestosterone linguets, and phenobarbital tablets. U. S. v. Black's Prescription Shop, Inc., Lorren R. Black, George E. Nicholas, and Virgil L. Haag. Pleas of nolo contendere. Corporation fined \$60, plus costs, Defendant Black fined \$60, and Defendants Nicholas and Haag each fined \$30. (F. D. C. No. 34341. Sample Nos. 14792-L, 14793-L, 14795-L, 14796-L, 14798-L, 14800-L.)

INFORMATION FILED: April 28, 1953, Western District of Missouri, against Black's Prescription Shop, Inc., Kansas City, Mo., and Lorren R. Black, president of