DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

3121. Misbranding of penicillin sodium. U. S. v. 696 Cartons, etc. (F. D. C. No. 23191. Sample Nos. 64198–H, 64199–H.)

LIBEL FILED: June 18, 1947, Southern District of New York.

ALLEGED SHIPMENT: On or about May 13, 1947, by Barich, Inc., from East Rutherford, N. J.

PRODUCT: 696 cartons, each containing 5 200,000-unit vials, and 9 cartons, each containing 5 500,000-unit vials, of *penicillin sodium* at New York, N. Y.

LABEL, IN PART: (Cartons) "Penicillin Sodium Proctor * * * Proctor Laboratories 475 Fifth Avenue New York 17, U. S. A."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was misleading since it failed to reveal the fact that Proctor Laboratories was not the manufacturer of the article, which fact was material in the light of the unmodified words "Proctor Laboratories" appearing in the labeling; and the label statements "Lot No. 77 * * * Oct–1–48" on the 200,000-unit vials and "Lot No. 90 * * * Oct 1 1948" on the 500,000-unit vials were misleading since they represented and suggested that the article had been certified under such identifying marks in accordance with regulations promulgated by the Federal Security Administrator, whereas the article had not been so certified.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (l), the article was represented as a drug composed wholly of *penicillin sodium*, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: June 1, 1950. The Proctor Laboratories having appeared as claimant and subsequently having withdrawn its claim, judgment of condemnation was entered and the court ordered that the product be destroyed.

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

3122. Misbranding of amytal tablets. U. S. v. Cosmopolitan Drug Co. and Charles M. Berman. Pleas of nolo contendere. Fine of $100 and costs against company; fine of $50 against individual. (F. D. C. No. 28103. Sample Nos. 42324–K, 43185–K, 43189–K.)

INFORMATION FILED: January 17, 1950, Northern District of Illinois, against the Cosmopolitan Drug Co., a partnership, Chicago, Ill., and Charles M. Berman, a pharmacist for the partnership.

INTERSTATE SHIPMENT: Between the approximate dates of October 20 and November 17, 1948, from the State of Indiana into the State of Illinois.

ALLEGED VIOLATION: On or about February 17, 18, and 23, 1949, while a number of *amytal tablets* were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the tablets to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged tablets being misbranded.

*See also No. 3121.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the tablets contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the repackaged tablets 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) (1), the repackaged tablets bore no labeling containing directions for use.

DISPOSITION: May 10, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of $100 and costs against the company and a fine of $50 against the individual.

3123. Misbranding of Carbrital capsules. U. S. v. McDowell's Pharmacy and John Vance McDowell. Pleas of guilty. Individual fined $500 on count 1 and assessed costs on counts 2 and 3; pharmacy also assessed costs, which were suspended. (F. D. C. No. 28128. Sample Nos. 19355–K, 52048–K, 52054–K.)

INFORMATION FILED: February 8, 1950, Northern District of Ohio, against the McDowell's Pharmacy, a partnership, Akron, Ohio, and John Vance McDowell, a partner in the partnership.

INTERSTATE SHIPMENT: Between the approximate dates of June 24 and August 8, 1947, from the State of Michigan into the State of Ohio.

ALLEGED VIOLATION: On or about June 10, 17, and 29, 1949, while a number of *Carbrital capsules* were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the capsules to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Carbrital capsules* contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the repackaged 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), the repackaged capsules bore no labeling containing directions for use.

DISPOSITION: June 7, 1950. Pleas of guilty having been entered, the court imposed a fine of $500 on count 1 and assessed costs in the amount of $21.10 on counts 2 and 3 against the individual defendant. The court also assessed costs in the amount of $21.10 against the partnership, which costs were suspended.

3124. Misbranding of sodium pentobarbital capsules and seconal sodium capsules. U. S. v. Jay Leonard Bumpas (Bumpas Drug Store), and Bailey Ammons. Pleas of nolo contendere. Fine of $250 against defendant Bumpas and $100 against defendant Ammons. (F. D. C. No. 28140. Sample Nos. 56043–K to 56046–K., incl., 56049–K.)