

chemical derivatives of barbituric acid, which derivatives have been by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules and tablets failed to bear 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 (f) (1), the repackaged *Nembutal Sodium capsules* and *thyroid tablets* failed to bear labeling containing adequate directions for use.

DISPOSITION: March 3, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$125.

**3206. Misbranding of Seconal Sodium capsules. U. S. v. John Byron Miller (J. B. Miller, pharmacist). Plea of guilty. Fine of \$225, plus costs. (F. D. C. No. 28130. Sample Nos. 43664-K, 43665-K, 51668-K.)**

INFORMATION FILED: May 18, 1950, Eastern District of Kentucky, against John Byron Miller, trading as J. B. Miller, pharmacist, Williamstown, Ky.

INTERSTATE SHIPMENT: From the State of Indiana into the State of Kentucky, of quantities of *Seconal Sodium capsules*.

ALLEGED VIOLATION: On or about June 14, 17, and 20, 1949, while the *Seconal Sodium capsules* were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the capsules to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged capsules 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.

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

DISPOSITION: September 25, 1950. A plea of guilty having been entered, the court imposed a fine of \$225, plus costs.

**3207 Misbranding of sulfathiazole tablets. U. S. v. Herman V. Baker (Baker's Cut Rate Drugs). Plea of nolo contendere. Fine, \$300. (F. D. C. No. 29119. Sample Nos. 48642-K, 48657-K, 48658-K.)**

INFORMATION FILED: June 8, 1950, Eastern District of Pennsylvania, against Herman V. Baker, trading as Baker's Cut Rate Drugs, Philadelphia, Pa.

INTERSTATE SHIPMENT: From the State of New York into the State of Pennsylvania, of quantities of *sulfathiazole tablets*.

ALLEGED VIOLATION: On or about October 24 and 28 and November 3, 1949, while the *sulfathiazole tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a prescription, which acts resulted in the tablets being misbranded.

**NATURE OF CHARGE:** Misbranding, Sections 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 statements 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, Section 502 (f) (2), they bore no 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.

**DISPOSITION:** August 17, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$300.

**3208. Misbranding of methyl testosterone tablets and alpha estradiol tablets.**  
**U. S. v. Norman N. Beil (Research Products). Plea of guilty. Fine of \$800, plus costs.** (F. D. C. No. 28120. Sample Nos. 2780-K, 3779-K, 12349-K, 24998-K.)

**INFORMATION FILED:** January 25, 1950, Northern District of Ohio, against Norman N. Beil, trading as Research Products, Cleveland, Ohio.

**ALLEGED SHIPMENT:** On or about January 27, 28, and 31, and February 10, 1949, from the State of Ohio into the States of Maryland, Virginia, Delaware, and South Dakota.

**LABEL, IN PART:** (Methyl testosterone tablets). "Male Hormone Tablets Each Tablet Contains 10 mg. [or "5 mg."] Methyl Testosterone For use when Methyl Testosterone is indicated for symptoms of Male Hormone Deficiency. Suggested Average Dose: One (1) tablet daily when the use of male hormones is directed by your physician. Warning: The male sex hormone should not be used if there is any indication of cancer of the prostate."

Accompanying 2 of the 3 shipments of *methyl testosterone tablets* were circulars entitled "The Male Hormone," and one of these shipments also was accompanied by an instruction sheet entitled "Important Instructions." The label of the *alpha estradiol tablets* (female hormones) had been destroyed by the consignee, but the consignment was accompanied by a copy of the circular entitled "The Male Hormone," which contained certain representations regarding the female hormone.

**NATURE OF CHARGE:** *Methyl testosterone tablets.* Misbranding, Section 502 (a), (2 shipments) certain statements in the labeling were false and misleading. The labeling represented and suggested that the article would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development, and depth of voice; that it would correct lack of sexual power and impotence; that it would relieve and postpone the many conditions associated with middle age, and would improve the sense of well-being; that it constituted for the average man in his late forties an adequate treatment for flushes, sweats, chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression and general weakness, and poor physical strength; that the use of the article would result in improved physical and mental work, and would exert a tonic action resulting in renewed vigor; and that the article would impart a better attitude toward social life, and would cause nervousness, exhaustion, and melancholy to disappear. The article would not be effective for such purposes. Further misbranding, Section 502 (f) (1), (all shipments) the labeling failed to bear adequate directions for use in that the directions for use appearing in the labeling were inadequate.