

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED  
ACCORDING TO DIRECTIONS**

**3181. Misbranding of methyl testosterone tablets. U. S. v. Louis Needman (West Coast Prescription Pharmacy). Plea of nolo contendere. Fine, \$50. (F. D. C. No. 28204. Sample Nos. 31524-K, 31527-K.)**

**INFORMATION FILED:** March 27, 1950, Southern District of California, against Louis Needman, trading as the West Coast Prescription Pharmacy, Los Angeles, Calif.

**INTERSTATE SHIPMENT:** Between the approximate dates of December 22, 1948, and June 15, 1949, from the State of New Jersey into the State of California.

**ALLEGED VIOLATION:** On August 4 and 8, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendant removed a number of *methyl testosterone tablets* from the bottle in which they had been shipped in interstate commerce and repacked them in a small bottle and sold them without a prescription; also, on August 8, the defendant sold a number of *methyl testosterone tablets* in the bottle in which they had been shipped in interstate commerce, after first relabeling the bottle, and sold them without a physician's prescription, which acts of the defendant resulted in the repackaged and relabeled tablets of drug being misbranded.

**NATURE OF CHARGE:** Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, in that each tablet contained 10 milligrams of methyl testosterone and the use of a drug containing 10 milligrams of methyl testosterone in each tablet with the frequency prescribed, recommended, and suggested in the labeling, namely, as directed on the labels, "1-2 linguets daily" and "1-2 daily," would be dangerous to health since such use of the article may result in sterility and would stimulate the growth of carcinoma of the prostate gland; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in that there was no statement in the labeling of any condition, disease, or function for which the article was to be used.

**DISPOSITION:** May 22, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$50.

**3182. Misbranding of Gattis worm oil. U. S. v. 120 Bottles \* \* \*. (F. D. C. No. 29216. Sample No. 72940-K.)**

**LIBEL FILED:** May 23, 1950, Western District of Kentucky.

**ALLEGED SHIPMENT:** On or about April 19, 1950, by the Gattis Chemical Co., from Nashville, Tenn.

**PRODUCT:** 120 1-ounce bottles of *Gattis worm oil* at Owensboro, Ky. Examination disclosed that the product had the composition stated on its label.

**LABEL, IN PART:** "Gattis Worm Oil Each Fluid Ounce Contains: 22 Mins. Oil Worm Seed 12 Mins. Chloroform 421 Mins. Castor Oil, Turpentine, Combined With Aromatics. Directions: Children 2 to 5 Years Old, One-Half Teaspoonful; 5 to 10 Years Old, One Teaspoonful; Adults, One And A Half Teaspoonfuls. One Dose Morning And Night (May Be Given For 2 Or 3 Days If Necessary)."

**NATURE OF CHARGE:** Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

**DISPOSITION:** July 3, 1950. Default decree of condemnation and destruction.

### NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

**3183. Misbranding of Stops (antihistamine tablets). U. S. v. 24 Display Cards, etc.** (F. D. C. No. 29249. Sample No. 67424-K.)

**LIBEL FILED:** June 7, 1950, Southern District of West Virginia.

**ALLEGED SHIPMENT:** On or about March 27, 1950, by the Research Associates, from Decatur, Ill.

**PRODUCT:** 24 display cards, each containing 26 packages, of *Stops* at Bluefield, W. Va., together with a number of window streamers entitled "Stops." Analysis showed that the product contained pyranisamine maleate.

**LABEL, IN PART:** (Package) "Stops 12 Anti-Histamine Tablets Each Tablet Contains 25 MG. Anisopyramine."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the statements "Stops Colds, Stops Coughs" appearing in the labeling of the article, namely, on the package label, display card, and window streamer, were false and misleading since the article was not an adequate and effective treatment for those conditions; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since pyranisamine maleate was not declared.

The article also was in violation of Section 505 (a), since it was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

**DISPOSITION:** June 28, 1950. Default decree of condemnation and destruction.

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

**3184. Misbranding of pentobarbital sodium capsules. U. S. v. C. Thomas Newell. Plea of nolo contendere. Fine, \$100.** (F. D. C. No. 28122. Sample Nos. 1852-K, 1858-K, 1860-K, 1864-K.)

**INFORMATION FILED:** April 1, 1950, Southern District of Florida, against C. Thomas Newell, pharmacist for the Everglades Pharmacy, Palm Beach, Fla.

**INTERSTATE SHIPMENT:** From the State of Illinois into the State of Florida, of quantities of *pentobarbital sodium capsules*.

**ALLEGED VIOLATION:** On or about June 3, 10, 24, and 29, 1949, while the drug was being held for sale at the Everglades Pharmacy after shipment in interstate commerce, C. Thomas Newell caused various quantities of the *pentobarbital sodium capsules* to be repacked and sold without a physician's prescription, which acts resulted in the capsules being misbranded.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (2), the repackaged capsules bore no label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by

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\* See also No. 3181.