

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

* See also No. 3181.

regulations designated as, habit forming; and the label 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 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since the directions for use "One capsule to induce sleep as directed," borne on the labeling, were not adequate directions for use.

DISPOSITION: July 28, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$100.

3185. Misbranding of sulfadiazine tablets, Seconal Sodium capsules, and thyroid tablets. U. S. v. Frank Albright (Albright Drug Store). Plea of nolo contendere. Fine of \$150, plus costs. (F. D. C. No. 29416. Sample Nos. 61661-K, 61662-K, 61736-K.)

INFORMATION FILED: July 7, 1950, Western District of Kentucky, against Frank Albright, trading as the Albright Drug Store, Paducah, Ky.

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

ALLEGED VIOLATION: On or about September 17 and 27, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused certain quantities of the drugs to be repacked and sold without a prescription, which acts resulted in the drugs being misbranded.

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

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which has been designated as habit forming; and when repackaged, the capsules bore no 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 (e) (1), the repackaged *sulfadiazine tablets* and *thyroid tablets* failed to bear labels containing the common or usual name of the drugs; Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* bore no labeling containing 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: July 20, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$150, plus costs.

3186. Misbranding of sulfathiazole tablets. U. S. v. Bowers' Pharmacy and Cloyce A. Bowers. Pleas of nolo contendere. Fine of \$100, plus costs, against defendants jointly. (F. D. C. No. 29112. Sample Nos. 15894-K, 15896-K, 60615-K.)

INFORMATION FILED: April 28, 1950, Northern District of Indiana, against the Bowers' Pharmacy, a partnership, Gary, Ind., and against Cloyce A. Bowers, a partner in the partnership.