

**NATURE OF CHARGE:** While the *thyroid tablets* were being held for sale at Neels Drugs after shipment in interstate commerce, William G. Neu, on or about August 17, 1949, caused a number of these tablets to be sold and disposed of, in the original bottles in which the tablets had been shipped in interstate commerce, without requiring a prescription of a physician. When received by the defendant, the label of the tablets bore the statement "Warning—To be dispensed only by or on the prescription of a physician," and as a result, the tablets were not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling. However, by selling the tablets without a prescription, the defendant caused the exemption to expire, resulting in the misbranding of the *thyroid tablets* in violation of Section 502 (f) (1), since the bottles bore no labeling containing directions for use.

In addition to the above sale, the defendant, on or about August 15 and 17, 1949, caused various quantities of *thyroid tablets*, *Benzedrine Sulfate tablets*, *Sulfonamides Triplex tablets*, *diethylstilbestrol tablets*, and *pentobarbital sodium capsules* to be repackaged and sold without a prescription while they were being held for sale at Neels Drugs after shipment in interstate commerce, which acts resulted in the repackaged drugs being misbranded as follows: Section 502 (b) (1), the repackaged drugs, other than the *diethylstilbestrol tablets*, failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and when repackaged they 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 repackaged *Benzedrine Sulfate tablets* failed to bear a label containing the common or usual name of the tablets; Section 502 (e) (2), the repackaged *Sulfonamides Triplex tablets* were fabricated from two or more ingredients, and they failed to bear a label containing the common or usual name of each active ingredient, namely, sulfamerazine, sulfadiazine, and sulfathiazole; Section 502 (f) (1), the labeling of all of the repackaged drugs, with the exception of the *Sulfonamides Triplex tablets*, failed to bear adequate directions for use; and, Section 502 (f) (2), the repackaged *Sulfonamides Triplex tablets* and the *diethylstilbestrol 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:** August 18, 1950. A plea of guilty having been entered, the court imposed a fine of \$1,000.

**3225. Misbranding of gelatin capsules and Newallium oleum capsules. U. S. v. 4 Cartons, etc. (F. D. C. No. 29392. Sample No. 81191-K.)**

**LIBEL FILED:** July 10, 1950, Eastern District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about September 14, 1949, by the Curtiss Candy Co., from Chicago, Ill.

**PRODUCT:** 4 cartons, each containing 10,000 capsules, and 144 100-capsule boxes, 72 50-capsule boxes, and 24 25-capsule boxes, of *Newallium oleum capsules* at Philadelphia, Pa., together with a number of folders entitled "Newallium Oleum" and "New Potent Antibiotic Reported in Garlic Newallium Oleum."

Analysis showed that the capsules contained a fatty oil, other than olive oil, and material derived from garlic.

**RESULTS OF INVESTIGATION:** The 4 cartons of the *gelatin capsules* were the remainder of an original shipment consisting of 10 cartons. After the receipt of such cartons by the consignee, R. M. Newcomb, Philadelphia, Pa., a number of the capsules were repackaged into the boxes described above. Information obtained at the time of the investigation indicated that the folders described above were printed in Philadelphia, Pa.

**LABEL, IN PART:** (Cartons) "Quantity: 10,000 Size: 6 minim Soluble gelatin capsules each containing .344 gram fill garlic and vegetable oils. Dosage: 2 capsules daily. \* \* \* W. G. Peacock Co. Evanston \* \* \* Illinois"; (boxes) "Newallium Oleum \* \* \* 6-Minim Capsules Concentrate of valuable factors in garlic infused in Olive Oil. \* \* \* One capsule twice daily with meals, or as directed by doctor. R. M. Newcomb Co. 5231 Chestnut St. Philadelphia 39, Pa."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article in the cartons failed to bear adequate directions for use. The article was misbranded in such respect when introduced into, and while in, interstate commerce.

Misbranding, Section 502 (a), the folders accompanying the article contained statements which represented and suggested that the article contained in the cartons and in the boxes was an adequate and effective treatment for high blood pressure, respiratory and intestinal catarrh, colitis, enteritis, diarrhea, and related ailments; that the article was a vermifuge for children or adults; that it would prevent and cure infections; that it was a bactericide when employed in the recommended dosage; that it would relieve headache and dizziness associated with high blood pressure; that it was an effective treatment for chronic enterocolitis, *Salmonella* infections, including paratyphoid; and that it was a kidney stimulant. The statements were false and misleading since the article was not an adequate and effective treatment for such conditions, and would not fulfill the other promises of benefit stated and implied; and the statement "Concentrate of valuable factors in garlic infused in Olive Oil" borne on the label of the article in the boxes was false and misleading since the article did not have the composition stated. The article was misbranded under Section 502 (a) while held for sale after shipment in interstate commerce.

**DISPOSITION:** July 26, 1950. R. M. Newcomb having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

**3226. Misbranding of Syno. U. S. v. 3 Bottles, etc. (F. D. C. No. 29014. Sample Nos. 59939-K, 59940-K.)**

**LABEL FILED:** March 21, 1950, Eastern District of Wisconsin.

**ALLEGED SHIPMENT:** On or about October 12, 1948, by Hubert H. Setzler, from Newberry, S. C.

**PRODUCT:** 3 full and 1 partially filled 1-gallon bottles and 67 2-fluid-dram bottles of *Syno* at Milwaukee, Wis., in possession of Syno Sales, Inc. The 2-fluid-dram bottles were filled with the product which was taken from part of the October 12 shipment.

Examination of samples showed that the product consisted essentially of chloroform, approximately 40 percent by volume, camphor, alcohol, water, a fatty oil, and a small proportion of free fatty acid.