

3222. Misbranding of Special tablets and Oxylin antiseptic tablets. U. S. v. 5,000 Tablets, etc. (F. D. C. No. 29314. Sample No. 81007-K.)

**LABEL FILED:** May 12, 1950, Eastern District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about February 12, 1950, by D. M. Olmstead Laboratories, from Camden, N. J.

**PRODUCT:** 5,000 Special tablets in bulk, and 19 100-tablet bottles, 9 200-tablet bottles, 6 500-tablet bottles, and 7 1,000-tablet bottles of *Oxylin antiseptic tablets*, at Upper Darby, Pa.

**RESULTS OF INVESTIGATION:** The tablets contained in the bottles were found to have been repacked by Meredith L. Evons, Upper Darby, Pa., from the bulk shipment mentioned above.

**LABEL, IN PART:** (Bulk shipment) "Special Tablets \* \* \* Each Tablet contains: Oxyquinoline sulfate 1.67 grs. Saccharine  $\frac{1}{4}$  gr. Oil Peppermint Oil Wintergreen Boric Acid q. s. 7.5 grs. C # 20650"; (repackaged tablets) "Oxylin Antiseptic Tablets \* \* \* Each tablet contains 1.67 grains of oxyquinoline sulfate (chinosol), also saccharine, winter green and peppermint. \* \* \* Internal Uses:—Oxylin Tablets are a valuable intestinal and urinary antiseptic, inhibit bacteria, arrest fermentation and allay irritation. Prescribed internally wherever intestinal or urinary antiseptics is desired. Indicated conditions are hyperacidity, intestinal toxemia, diarrhea, amebic and bacillary dysentery, bed wetting, gonorrhoea (in solution for irrigation and orally), nephritis, pyelitis, cystitis, pyuria. Lauded as a specific for intestinal grippe, influenza and common cold. Dosage—Adults 3 tablets swallowed with water on an empty stomach, 3 or 4 times daily. In acute or stubborn cases, increase dosage to three tablets every two hours. Children, one tablet, four times daily, may be dissolved in water. Do not chew the tablets."

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

Misbranding (tablets in bottles), Section 502 (a), the label of the article contained statements which represented and suggested that the article was useful for intestinal or urinary antiseptics, and to arrest fermentation and allay irritation, and was an adequate treatment for hyperacidity, intestinal toxemia, diarrhea, amebic and bacillary dysentery, bed wetting, gonorrhoea, nephritis, pyelitis, cystitis, pyuria, intestinal grippe, influenza, and the common cold, which statements were false and misleading since the article was not useful nor an adequate treatment for the conditions stated and implied; 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 the active ingredient, boric acid; and, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling. The article in the bottles was misbranded in the respects indicated while held for sale after shipment in interstate commerce.

**DISPOSITION:** June 20, 1950. Default decree of condemnation and destruction.

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

**3223. Misbranding of Benzedrine Sulfate tablets, Seconal Sodium capsules, Sulfonamides Triplex tablets and Benadryl Hydrochloride capsules. U. S. v. Edwin L. Martin (Martin's Drug Store). Plea of nolo contendere. Defendant placed on probation for 1 year. (F. D. C. No. 26732. Sample Nos. 45577-K to 45580-K, incl., 45969-K, 45970-K, 45973-K, 46181-K.)**

**INFORMATION FILED:** September 26, 1949, Western District of Arkansas against Edwin L. Martin, trading as Martin's Drug Store, Hot Springs, Ark.

**INTERSTATE SHIPMENT:** Between the approximate dates of May 12 and December 20, 1948, from the States of Missouri, Indiana, and Pennsylvania, into the State of Arkansas.

**ALLEGED VIOLATION:** On or about December 28, 1948, and February 4, 5, and 12, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets and capsules to be removed from the bottles in which they had been shipped, and to be repacked and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (2), the labels of the repackaged drugs bore no statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the drugs bore no directions for use.

Further misbranding, Section 502 (d), the *Seconal Sodium* was a drug for use by man and 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 the labels of the repackaged drug 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) (2), the repackaged *Sulfonamides Triplex tablets* were fabricated from two or more ingredients, and the label of the repackaged tablets failed to bear the common or usual name of each active ingredient, namely sulfathiazole, sulfadiazine, and sulfamerazine; and, Section 502 (f) (2), the repackaged *Sulfonamides Triplex tablets* bore no labeling containing adequate warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

**DISPOSITION:** October 3, 1949. A plea of nolo contendere having been entered, the court placed the defendant on probation for 1 year.

**3224. Misbranding of thyroid tablets, Benzedrine Sulfate tablets, Sulfonamides Triplex tablets, diethylstilbestrol tablets, and pentobarbital sodium capsules. U. S. v. William G. Neu. Plea of guilty. Fine, \$1,000. (F. D. C. No. 29434. Sample Nos. 60942-K to 60945-K, incl., 60948-K, 60949-K.)**

**INFORMATION FILED:** July 25, 1950, Eastern District of Missouri, against William G. Neu, a pharmacist for Neels Drugs, St. Louis, Mo.

**INTERSTATE SHIPMENT:** From the States of Michigan, Pennsylvania, Indiana, and New York, into the State of Missouri, of quantities of *thyroid tablets*, *Benzedrine Sulfate tablets*, *Sulfonamides Triplex tablets*, *diethylstilbestrol tablets*, and *pentobarbital sodium capsules*.

\*See also Nos. 3221, 3222.