DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2791. Misbranding of syrup urethane. U. S. v. 94 Bottles * * * (and 1 other seizure action). (F. D. C. Nos. 26645, 26647. Sample Nos. 11186–K, 11187–K.)

LIBELS FILED: On or about March 11 and 17, 1949, Eastern and Southern Districts of New York.

ALLEGED SHIPMENT: Between the approximate dates of November 29, 1948, and February 16, 1949, by Marvin R. Thompson, Inc., from Stamford, Conn.

PRODUCT: 94 16-ounce bottles and 12 1-gallon bottles of *syrup urethane* at Brooklyn and New York, N. Y.

LABEL, IN PART: "Syrup Urethane * * * Each teaspoonful (5-cc) contains urethane 4 Grs. in a flavored syrup base. Directions: 1 teaspoonful every 3 or 4 hours, or as directed by the physician."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling, namely, "1 teaspoonful every 3 or 4 hours," since the administration every 3 or 4 hours of 1 teaspoonful of the article containing the stated amount of urethane is capable of causing leucopenia.

Further misbranding, Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to Section 505 (b) of the law was not effective with respect to the article.

DISPOSITION: April 22 and May 9, 1949. Default decrees of condemnation and destruction.

2792. Misbranding of vaginal suppositories. U. S. v. 34 Boxes * * *. (F. D. C. No. 27058. Sample Nos. 29261–K, 29262–K.)

LIBEL FILED: April 27, 1949, District of Colorado.

ALLEGED SHIPMENT: On or about October 28, 1946, and January 20, 1949, by the South Bend Remedy Co., from San Mateo, Calif.

PRODUCT: 34 boxes of *vaginal suppositories* at Denver, Colo. Examination of samples showed that each suppository contained not less than 36 percent of potassium alum.

LABEL, IN PART: "Magnolia Blossom 6 Vaginal Suppositories."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "For minor vaginal irritations" appearing on the label of a portion of the article was false and misleading since the article would not be effective in relieving irritations but would produce an irritation; and, Section 502 (j), the article was dangerous to health when used with the frequency or duration recommended or suggested in the labeling thereof, namely, "insert one suppository into the vagina * * * and leave undisturbed for seventy two hours."

DISPOSITION: June 1, 1949. Default decree of condemnation and destruction.

2793. Misbranding of Gattis' Worm Oil. U. S. v. 60 Bottles * * * (and 1 other seizure action). (F. D. C. Nos. 27002, 27003. Sample Nos. 1640–K, 1641–K.)

LIBELS FILED: April 14, 1949, Western District of North Carolina.

ALLEGED SHIPMENT: On or about January 5 and February 19, 1949, by the Gattis Chemical Co., from Nashville, Tenn.

PRODUCT: 186 bottles of *Gattis' Worm Oil* at Asheville, N. C. Analysis showed 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.) * * * Net Contents 1 Fl. Oz."

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

DISPOSITION: May 31, 1949. Default decree of condemnation and destruction.

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

2794. Misbranding of benzedrine sulfate tablets and benadryl hydrochloride kapseals. U. S. v. Harry Kaplan, pharmacist for Fienup's Drug Co. Plea of guilty. Fine, $501. (F. D. C. No. 26289. Sample Nos. 27025–K, 27745–K.)

INFORMATION FILED: December 14, 1948, Eastern District of Missouri, against Harry Kaplan, a pharmacist for Fienup's Drug Co., St. Louis, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of January 22 and April 30, 1948, from Philadelphia, Pa., and Detroit, Mich., to St. Louis, Mo., of a number of bottles of *benzedrine sulfate tablets* and *benadryl hydrochloride kapseals.*

LABEL, WHEN SHIPPED: "Benzedrine Sulfate Tablets [or "Kapseals Benadryl Hydrochloride"] * * * Caution: To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about May 26 and June 2, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be removed from the bottles in which they had been shipped, repacked the drugs into boxes, and sold them without a prescription, which acts by the defendant resulted in the repackaged drugs being misbranded. The repackaged *benzedrine sulfate tablets* were unlabeled. The repackaged *benadryl hydrochloride kapseals* were labeled "Benadryl 50 Mgn."

Misbranding, Section 502 (b) (1), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged drugs bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the boxes containing the repackaged drugs bore no labeling containing directions for use. Further misbranding, Section 502 (e) (2), the repackaged *benzedrine sulfate tablets* were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and they failed to bear a label showing the common or usual name of the active ingredient.