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. 11186–1187–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.