

3710. Misbranding of sulfadiazine tablets, Ergoapiol with savin capsules, and methyltestosterone linguets. U. S. v. Harmon S. Cover (Wiechelman Drugs), and Joseph Ralenkotter. Pleas of guilty. Harmon S. Cover fined \$75 and Joseph Ralenkotter fined \$25. (F. D. C. No. 32739. Sample Nos. 84690-K, 84929-K, 84957-K.)

INFORMATION FILED: February 28, 1952, Eastern District of Kentucky, against Harmon S. Cover, trading as Wiechelman Drugs at Covington, Ky., and Joseph Ralenkotter, a pharmacist for Wiechelman Drugs.

INTERSTATE SHIPMENT: Prior to the date of the sales referred to below, quantities of *sulfadiazine tablets*, *Ergoapiol with savin capsules*, and *methyltestosterone linguets* were shipped in interstate commerce into the State of Kentucky.

ALLEGED VIOLATION: On or about August 3, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of capsules of *Ergoapiol with savin* to be sold and dispensed to a purchaser in the original box in which the capsules had been shipped in interstate commerce, without the prescription of a physician; and on or about December 8 and 14, 1950, the defendants repacked various quantities of *sulfadiazine tablets* and *methyltestosterone linguets* and sold the repackaged drugs without prescriptions, which acts of the defendants resulted in the drugs being misbranded.

Harmon S. Cover was charged with causing the violations involved in all counts, and Joseph Ralenkotter was joined in one count of the information and charged with the violation involved in that count.

NATURE OF CHARGE: *Ergoapiol with savin capsules.* Misbranding, Section 502 (f) (1), the labeling of the drug bore no directions for use. (The box in which the capsules were shipped in interstate commerce bore no directions for use since it was exempted from such requirement by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendants in dispensing the drug without a physician's prescription caused the exemption to expire.)

Sulfadiazine tablets and *methyltestosterone linguets.* Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Sulfadiazine tablets. Misbranding, Section 502 (e) (1), the drug failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling failed to bear adequate 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, in such manner and form, as are necessary for the protection of users.

DISPOSITION: March 10, 1952. Pleas of guilty having been entered, the court fined Harmon S. Cover \$75 and Joseph Ralenkotter \$25.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3711. Adulteration of passion flower herb and gelsemium root. U. S. v. 32 Bales, etc. (F. D. C. No. 32854. Sample Nos. 12096-L, 12097-L.)

LABEL FILED: March 7, 1952, Southern District of Indiana.

ALLEGED SHIPMENT: On or about September 29, 1949, and October 4, 1951, from Boone and Statesville, N. C.

PRODUCT: 32 300-pound bales of *passion flower herb* and 8 340-pound bales of *gelsemium root* at Tipton, Ind., in possession of the Inland Alkaloid Co.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances (the *passion flower herb* contained rodent excreta, rodent hairs, and insects, and the *gelsemium root* contained rodent hairs and insect fragments); and, Section 501 (a) (2), the *gelsemium root* had been held under insanitary conditions whereby it may have become contaminated with filth. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: June 2, 1952. The Inland Alkaloid Co. having consented to the destruction of the products, judgment of forfeiture was entered and the court ordered that the products be destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3712. Adulteration and misbranding of procaine penicillin G. U. S. v. 647 Vials, etc. (F. D. C. No. 31977. Sample Nos. 18292-L to 18294-L, incl.)

LIBEL FILED: November 7, 1951, District of Arizona.

ALLEGED SHIPMENT: On or about May 29, 1951, from San Francisco, Calif.

PRODUCT: *Procaine penicillin G.* 837 10-cc. vials, and 14 boxes, each containing 1-cc. cartridge, at Phoenix, Ariz.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements (837-vial lot) "10 cc. size * * * 3,000,000 units * * * Each cc contains 300,000 units" and (14-box lot) "1 cc. size (300,000 Units)" were false and misleading since the potency of the article was less than stated on the labels.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 21, 1952. Default decree of condemnation and destruction.

3713. Adulteration and misbranding of Liv-Vi-B. U. S. v. 24 Vials * * *
(F. D. C. No. 32874. Sample No. 39833-L.)

LIBEL FILED: March 12, 1952, Southern District of California.

ALLEGED SHIPMENT: On or about April 9, June 30, and December 13, 1948, from Passaic, N. J.

PRODUCT: 24 10-cc. vials of *Liv-Vi-B* at Los Angeles, Calif. Analysis showed that the product contained approximately 59 percent of the declared amount of thiamine hydrochloride.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "Each 1 cc. contains * * * not less than 10 mgms. (3330 units) thiamine hydrochloride" was false and misleading as applied to the article, which contained less than 10 milligrams (3,330 units) of thiamine hydrochloride.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 7, 1952. Default decree of condemnation and destruction.