

DISPOSITION: On April 11, 1947, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2164. Adulteration of ampules of sodium salicylate and iodide with colchicine. U. S. v. 32 Boxes * * *. (F. D. C. No. 19571. Sample No. 35944-H.)

LIBEL FILED: On or about April 10, 1946, Western District of Missouri.

ALLEGED SHIPMENT: On or about December 3, 1945, by the National Drug Company, from Philadelphia, Pa.

PRODUCT: 32 25-ampule boxes of *ampules of sodium salicylate and iodide with colchicine* at St. Joseph, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampules of Sodium Salicylate and Iodide with Colchicine," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: August 20, 1946. Default decree of destruction.

2165. Adulteration of ampules of sodium thiosulfate. U. S. v. 168 Ampules * * *. (F. D. C. No. 12690. Sample No. 81332-F.)

LIBEL FILED: On or about July 1, 1944, District of Kansas.

ALLEGED SHIPMENT: On or about May 8, 1944, by Henry C. Haist and Co., from Kansas City, Mo.

PRODUCT: 158 10-milliliter-size *ampules of sodium thiosulfate*, at Wichita, Kans.

LABEL, IN PART: "A Sterile Isotonic Solution Compounded Especially for Intravenous Administration."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampules of Sodium Thiosulfate," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: June 25, 1944. The consignee, the sole intervener, having filed an answer admitting that the product was adulterated as alleged in the libel, judgment of condemnation was entered and the product was ordered destroyed.

2166. Adulteration of theelin in oil. U. S. v. 116 Packages * * *. (F. D. C. No. 21110. Sample No. 49472-H.)

LIBEL FILED: September 26, 1946, Northern District of Alabama.

ALLEGED SHIPMENT: On or about June 7, 10, and 20, 1946, by Parke, Davis & Co., from Detroit, Mich.

PRODUCT: 116 packages, each containing 50 ampules, of *theelin in oil* at Birmingham, Ala. Analysis showed that the product contained not less than .7 milligram of theelin (keto-hydroxy estratriene) and possessed a potency of not less than 7,000 International Units per cubic centimeter.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, i. e., .5 milligram theelin keto-hydroxy estratriene per cubic centimeter (5,000 International Units).

DISPOSITION: April 16, 1947. Parke, Davis & Company, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for reprocessing and disposal under the supervision of the Federal Security Agency.

2167. Adulteration and misbranding of Jarmilla Scalp Conditioner. U. S. v. 289 Jars * * *. (F. D. C. No. 22185. Sample No. 64763-H.)

LIBEL FILED: January 15, 1947, District of New Jersey.

ALLEGED SHIPMENT: On or about August 28 and October 19, 1946, by Jarmilla Products, Inc., from Lake Worth, Fla.

PRODUCT: 225 5½-ounce jars and 64 2-ounce jars of *Jarmilla Scalp Conditioner* at Elizabeth, N. J. Examination showed that the product consisted essentially of yellow mercuric oxide in an ointment base. The smaller size jars of the product contained less than the declared 5 percent of mercuric

oxide, and bacteriological examination showed that the article was not a germicide.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, i. e., by the designation "Germicidal Preparation."

Misbranding, Section 502 (a), the label statement "Scalp Conditioner A Germicidal Preparation for the Treatment of Scalp Disorders" was false and misleading since the article was not a germicide, was not effective for conditioning the scalp, and would not be effective in the treatment of scalp disorders; and, Section 502 (e) (2), the 2-ounce size jar failed to bear a statement of the quantity or proportion of the derivative of mercury contained in the article since the label statement "Mercuric Oxide Yellow U. S. P. 5%" was incorrect.

DISPOSITION: May 5, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2168. Adulteration and misbranding of prophylactics. U. S. v. 23½ Gross * * *.
(F. D. C. No. 22632. Sample No. 61322-H.)

LABEL FILED: March 13, 1947, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 14, 1947, by the World Merchandise Exchange and Trading Co., from New York, N. Y.

PRODUCT: 23½ gross of rubber *prophylactics* at Pittsburgh, Pa. Examination of 200 samples showed that 4.5 percent were defective in that they contained holes.

LABEL, IN PART: "Lloyd's Prophylactics."

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

Misbranding, Section 502 (a), the statement "Prophylactics" was false and misleading as applied to an article which contained holes.

DISPOSITION: April 23, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

2169. Misbranding of estrogenic substances. U. S. v. Harvey Laboratories, Inc., and Aaron Lichten. Pleas of nolo contendere. Fines of \$150 against the corporation and \$1 against the individual. (F. D. C. No. 21424. Sample Nos. 5150-H, 7816-H, 8301-H.)

INFORMATION FILED: January 16, 1947, Eastern District of Pennsylvania, against Harvey Laboratories, Inc., Philadelphia, Pa., and Aaron Lichten, treasurer of the corporation.

ALLEGED SHIPMENT: On or about October 19 and 30 and November 1, 1945, from the State of Pennsylvania into the States of New Jersey and New York.

LABEL, IN PART: (Cartons—all shipments, and vials—1 shipment) "Estrogenic Substances [or "Substance"] * * * estrogenic hormones from natural sources, consisting chiefly of estrone with traces of estradiol and auxiliary follicular hormones"; (ampules—2 shipments) "Estrogenic Substance 10,000 [or "50,000"] International Units Per cc."

NATURE OF CHARGE: Misbranding, Section 502 (a), the above-quoted statements on the cartons and vial labels were false and misleading since they represented and suggested that the article consisted chiefly of estrone, whereas it did not consist chiefly of estrone.

Further misbranding, Section 502 (e), the article was not designated solely by a name recognized in an official compendium; it was fabricated from 2 or more ingredients; and the ampule labels failed to bear the common or usual name of each active ingredient, since the designation "Estrogenic Substance" is not the common or usual name of any particular active ingredient but is a generic name for a class of substances.

* See also Nos. 2151, 2153-2155, 2158, 2159, 2163, 2167, 2168.