

since it was represented to contain 100 milligrams of thiamine hydrochloride per cubic centimeter, whereas it contained not more than 77.5 milligrams of thiamine hydrochloride per cubic centimeter.

Misbranding, Section 502 (a), the label statement, "Each cc. containing 100 mgm. Thiamine Hydrochloride," was false and misleading.

DISPOSITION: September 13, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$50 on each of the 2 counts of the information, a total fine of \$100.

1767. Adulteration and misbranding of Folestrin Suppositories and pituitary liquid. U. S. v. Armour and Co. (The Armour Laboratories). Plea of guilty. Fine, \$1,000 and costs. (F. D. C. No. 14215. Sample Nos. 39168-F, 54610-F.)

INFORMATION FILED: June 13, 1945, Northern District of Illinois, against Armour and Co., a corporation, trading as the Armour Laboratories, Chicago, Ill.

ALLEGED SHIPMENT: November 1 and 26, 1943, from the State of Illinois into The State of Indiana.

LABEL, IN PART: "Armour * * * Folestrin," and "Armour * * * Pituitary Liquid."

NATURE OF CHARGE: *Folestrin*. Adulteration, Section 501 (c), the strength of the article fell below that which it purported and was represented to possess, since each suppository was represented to contain 2,000 International Units of estrone, whereas each suppository contained not more than 500 International Units of estrone. Misbranding, Section 502 (a), the label statement, "Each Suppository Contains 2,000 International Estrogenic Units," was false and misleading since it represented and suggested that each suppository contained 2,000 International Units of estrone, whereas each suppository contained not more than 500 International Units of estrone.

Pituitary Liquid. Adulteration, Section 501 (d), a preparation of posterior pituitary having a potency per cubic centimeter of materially less than 20 U. S. P. posterior pituitary units had been substituted for pituitary liquid having a potency of 20 U. S. P. posterior pituitary units per cubic centimeter, which the article was represented to be. Misbranding, Section 502 (a), the label statements, "Pituitary Liquid Double Strength Solution of Posterior Pituitary Injection U. S. P. XII 20 U. S. P. Units Per cc," and "The Strength of This Solution is Double That of the Official U. S. P. Preparation 20 U. S. P. Units Per cc," were false and misleading since the article did not possess a potency of double that possessed by posterior pituitary injection of the official standard, but possessed a potency of not more than two-thirds of that claimed; and each cubic centimeter of the article did not contain 20 U. S. P. posterior pituitary units but contained not more than $13\frac{1}{3}$ posterior pituitary units.

DISPOSITION: September 24, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$1,000 and costs.

1768. Adulteration and misbranding of estrogenic substance in oil and estrogenic hormones. U. S. v. 70 Vials of Estrogenic Hormones (and 2 other seizure actions against estrogenic hormones and estrogenic substance). Decree of condemnation. Products ordered released under bond. (F. D. C. Nos. 15881, 15882, 15897. Sample Nos. 3826-H, 3828-H, 3905-H.)

LABELS FILED: April 6 and 12, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: Between the approximate dates of December 8, 1944, and February 23, 1945, by the Pro-Medico Laboratories, Inc., from Brooklyn, N. Y.

PRODUCT: 70 vials and 5,895 ampuls of *estrogenic hormones* and 4 bottles of *estrogenic substance* at Philadelphia, Pa. Examination showed that the estrogenic material present in the product consisted essentially of estradiol with no significant proportion of estrone.

LABEL, IN PART: (Vials) "20 cc. Estrogenic Hormones Multiple Dose Vial A sterile solution in ampul oil of estrogenic substances derived from equine urine"; (ampuls) "1 cc. Estrogenic Hormones * * * Professional Prod. Co., Phila., Pa. Dist.;" and (bottles) "Estrogenic Substance in Oil. Each cc contains Estrogenic Substance derived from equine urine."

NATURE OF CHARGE: Adulteration, Section 501 (d), 70-vial lot and 4-bottle lot, a preparation containing estrogenic material including little or no estrone had been substituted in whole or in part for a preparation containing estrogenic substances as they occur in equine urine.

Misbranding, Section 502 (a), the statement on the label of the 4-bottle lot, "contains estrogenic substance derived from equine urine," was misleading since the estrogenic material in the article was not composed of estrogenic material as it occurs in equine urine; and, Section 502 (e) (2), the label of the article in the 5,895-ampul lot failed to bear the common or usual name of each active ingredient since the term "Estrogenic Hormones" is the name of a group of chemical compounds and not the specific name of any particular hormone.

DISPOSITION: October 11, 1945. The Pro-Medico Laboratories, Inc., claimant, having admitted the allegations of the libels, and the cases having been consolidated, judgment of condemnation was entered and the products were ordered released under bond for relabeling under the supervision of the Federal Security Agency.

1769. Adulteration of estrogenic substance powder and adulteration and misbranding of estrogenic hormones. U. S. v. 1 Bottle of Estrogenic Substance Powder and 2 Vials of Estrogenic Hormone. Decrees of condemnation. One product ordered released under bond. (F. D. C. Nos. 16386, 16441. Sample Nos. 16552-H, 31329-H.)

LIBELS FILED: June 6 and 14, 1945, Southern District of California and Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about July 7, 1944, and April 9, 1945, by the Hema Drug Co., Inc., from Maspeth, N. Y.

PRODUCT: 2 vials of *estrogenic hormone* and 1 bottle of *estrogenic substance powder* at Woodworth, Wis., and Pasadena, Calif., respectively.

LABEL, IN PART: "Estrogenic Hormone 12 Grams," or "12 Grams Natural Estrogenic Substance Powder. Consists principally of estrone, estriol and estradiol with auxiliary hormones * * * as found in pregnant mares' urine."

NATURE OF CHARGE: *Estrogenic hormone.* Adulteration, Section 501 (d), a substance consisting largely of cholesterol, with relatively small proportions of estrone and estradiol, had been substituted in whole or in part for estrogenic hormone. Misbranding, Section 502 (a), the label statement "Estrogenic Hormone" was false and misleading.

Estrogenic substance powder. Adulteration, Section 501 (d), a substance consisting largely of cholesterol, with estradiol and a relatively small proportion of estrone, had been substituted in whole or in part for natural estrogenic substance powder consisting principally of estrone, estriol, and estradiol with auxiliary hormones as found in pregnant mares' urine.

DISPOSITION: August 24 and September 6, 1945. The Hema Drug Co., Inc., having appeared as claimant for the *estrogenic substance powder* and having consented to the entry of a decree, and no claim having been entered for the *estrogenic hormone*, judgments of condemnation were entered. The *estrogenic substance powder* was ordered released under bond for relabeling in conformity with the law, under the supervision of the Federal Security Agency. The *estrogenic hormone* was destroyed.

1770. Adulteration of water for injection. U. S. v. 112 Ampuls of Water for Injection. Default decree of destruction. (F. D. C. No. 16418. Sample No. 12989-H.)

LIBEL FILED: June 11, 1945, Southern District of Ohio.

ALLEGED SHIPMENT: On or about February 1, 1945, from Philadelphia, Pa., by Sharp and Dohme, Inc.

PRODUCT: 112 ampuls of *water for injection* at Columbus, Ohio.

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

DISPOSITION: September 18, 1945. No claimant having appeared, judgment was entered ordering that the product be destroyed.

1771. Adulteration of water for injection. U. S. v. 2 Boxes Containing 200 Ampuls of Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 13738. Sample No. 86931-F.)

LIBEL FILED: September 29, 1944, Northern District of Illinois.

ALLEGED SHIPMENT: On or about September 6, 1944, by the Metropolitan Laboratories, from New York, N. Y.