

PRODUCT: 16 cartons, each containing 25 ampules, of *calcium gluconate* in possession of the Meredyth Co., Washington, D. C.

LABEL, IN PART: (Ampules) "Intravenous Intramuscular * * * Medicinals, Inc. Richmond Hill, N. Y."; (cartons) "Ampules Medi-Gluconate 10%."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Calcium Gluconate 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 not clear and was not free of turbidity and undissolved material, as is required by the Pharmacopoeia.

DISPOSITION: January 17, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2067. Adulteration of iron cacodylate. U. S. v. 39 Vials of Iron Cacodylate. Default decree of condemnation and destruction. (F. D. C. No. 21912. Sample No. 65266-H.)

LIBEL FILED: December 3, 1946, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 1, 1946, by Medicinals, Inc., from Richmond Hill, N. Y.

PRODUCT: 39 vials, each containing 100 cc., of a solution of *iron cacodylate* at Philadelphia, Pa.

LABEL, IN PART: "Sterile Solution Iron Cacodylate * * * Dosage 5 cc. intravenously."

NATURE OF CHARGE: Adulteration, Section 501 (c), the article was a drug represented for intravenous administration, and its purity and quality fell below that which it was represented to possess, since it was contaminated with undissolved material. A drug for intravenous administration should not contain undissolved material.

DISPOSITION: January 28, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2068. Adulteration of estrogenic substance. U. S. v. 13 Vials of Estrogenic Substance. Default decree of condemnation and destruction. (F. D. C. No. 22334. Sample No. 49347-H.)

LIBEL FILED: December 27, 1946, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about August 19, 1946, by the C. B. Kendall Co., from Indianapolis, Ind.

PRODUCT: 13 vials of a solution of *estrogenic substance* at New Orleans, La. Examination showed that the estrogens present in the product did not consist of estrogens as they occur in, and are extracted from, pregnant mares' urine.

LABEL, IN PART: "Vial Sterile Solution Estrogenic Substance A purified preparation of naturally occurring estrogenic substances from pregnant mare's urine."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, estrogenic material different from that occurring in pregnant mares' urine, had been substituted in whole or in part for naturally occurring estrogenic substances from pregnant mares' urine, which the article was represented to be.

DISPOSITION: January 31, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2069. Adulteration and misbranding of estrogenic substance. U. S. v. 1 Bottle of Estrogenic Substance. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 16172. Sample No. 13570-H.)

LIBEL FILED: May 12, 1945, Southern District of Ohio.

ALLEGED SHIPMENT: On or about February 1, 1945, by W. F. Straub and Co., from Chicago, Ill.

PRODUCT: 1 bottle of *estrogenic substance* at Columbus, Ohio. Examination showed that the potency of the article was not more than 5,600,000 International Units of estrone per gram.

LABEL, IN PART: Estrogenic Substances 55.55 Grams Lot #00662 Whole Natural Crystalline Estrogenic Hormones from Pregnant Mares' Urine consisting mainly of Estrone and Estradiol, 9,000,000 I. U. per Gram."

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

Misbranding, Section 502 (a), the statement on the label, "Estrogenic Hormones from Pregnant Mares' Urine consisting mainly of Estrone and Estradiol, 9,000,000 I. U. per Gram," was false and misleading as applied to the article, the potency of which was not more than 5,600,000 International Units of estrone per gram.

DISPOSITION: June 29, 1945. The Borden Co. and W. F. Straub & Co., claimants, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

2070. Adulteration of isotonic solution of sodium chloride. U. S. v. 3,800 Vials of Isotonic Solution of Sodium Chloride. Default decree of condemnation and destruction. (F. D. C. No. 21866. Sample Nos. 38879-H, 39515-H.)

LIBEL FILED: December 19, 1946, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about June 29, 1946, by the Cheplin Biological Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 3,800 20-cc. vials of *isotonic solution of sodium chloride* at Milwaukee, Wis.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sterile Isotonic Solution of Sodium Chloride for Parenteral Use," 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: January 13, 1947. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2071. Adulteration of sodium iodide, sodium thiosulfate, and Hormegen. U. S. v. 11 Boxes of Sodium Iodide Ampuls, 3 Boxes of Sodium Thiosulfate Ampuls, and 2 Boxes of Hormegen Ampuls. Default decrees of condemnation and destruction. (F. D. C. Nos. 20767, 21586. Sample Nos. 54227-H, 54228-H, 65169-H.)

LIBELS FILED: On or about September 16 and October 30, 1946, Southern District of Florida and Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 30, 1945, and July 11 and 18, 1946, by the Estro Chemical Co., Inc., from New York, N. Y.

PRODUCT: 11 boxes, each containing 25 ampuls, of *sodium iodide* and 3 boxes, each containing 25 ampuls, of *sodium thiosulfate* at Miami, Fla., and 1 box, containing 100 ampuls, and 1 box, containing 6 ampuls, of *Hormegen* at Philadelphia, Pa. Examination showed that the ampuls of *sodium iodide* and *sodium thiosulfate* contained undissolved material, and that the potency of the *Hormegen* was equivalent to 82,500 International Units of estrone per cubic centimeter.

LABEL, IN PART: "Sodium Iodide 15½ grs. Intravenous," "Sodium Thiosulfate 10% Intravenous," or "Ampul 1 cc. Size Hormegen 50,000 I. U. * * * Distributed by Physicians' Drug & Supply Co. Philadelphia, Pa."

NATURE OF CHARGE: *Sodium iodide and sodium thiosulfate.* Adulteration, Section 501 (b), the articles purported to be and were represented as "Ampuls of Sodium Iodide" and "Ampuls of Sodium Thiosulfate," drugs the names of which are recognized in the National Formulary, an official compendium, but their quality and purity fell below the official standard since they were contaminated with undissolved material.

Hormegen. Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., "Each cc. is biologically standardized to a potency equivalent to 50,000 I. U. of Estrone U. S. P."

DISPOSITION: November 26 and December 9, 1946. No claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

2072. Adulteration and misbranding of thiamine chloride tablets. U. S. v. 501½ Dozen Bottles of Thiamin Chloride Tablets. Consent decree of condemnation and destruction. (F. D. C. No. 15393. Sample Nos. 66982-F, 20109-H to 20113-H, incl.)

LIBEL FILED: On or about February 24, 1945, Western District of Missouri.