DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2698. Adulteration of dextrose in isotonic solution of sodium chloride. U. S. v. 75 Flasks * * *. (F. D. C. No. 25156. Sample No. 54–K.)

LIBEL FILED: August 2, 1948, Eastern District of South Carolina.

ALLEGED SHIPMENT: On or about December 3, 1947, from Lakewood, Ohio.

PRODUCT: 75 flasks of *dextrose in isotonic solution of sodium chloride* at Columbia, S. C.

LABEL, IN PART: "Dextrose 10% W/V in Isotonic Solution of Sodium Chloride."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Dextrose and Sodium Chloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 28, 1948. Default decree of condemnation and destruction.

2699. Adulteration of ampuls of aminophylline and ampuls of sodium iodide and sodium salicylate with colchicine. U. S. v. 75 Cartons, etc. (F. D. C. No. 25354. Sample Nos. 10667–K, 10668–K.)

LIBEL FILED: August 12, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about July 7, 1948, by Bristol Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 75 cartons each containing 1 circular and 1 ampul of *aminophylline* and 75 cartons each containing 1 ampul of *sodium iodide and sodium salicylate with colchicine* at Elizabeth, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented, respectively, as "Aminophylline Injection," a drug the name of which is recognized in the United States Pharmacopoeia, and as "Sodium Salicylate and Iodide with Colchicine Ampuls," a drug the name of which is recognized in the National Formulary, and the quality and purity of the articles fell below the official standards since the articles were contaminated with undissolved material.

DISPOSITION: May 16, 1949. Default decree of condemnation and destruction.

2700. Adulteration of ampuls of iron cacodylate and thiamine. U. S. v. 250 Ampuls * * *. (F. D. C. No. 26257. Sample No. 28064–K.)

LIBEL FILED: January 24, 1949, District of New Mexico.

ALLEGED SHIPMENT: On or about October 19, 1948, from Kansas City, Mo.

PRODUCT: 250 ampuls of *iron cacodylate and thiamine* at Albuquerque, N. Mex.

LABEL, IN PART: "Iron Cacodylate and Thiamine 5 cc. * * * A sterile aqueous solution. For Intravenous Injection."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, namely, "Sterile solution For Intravenous Injection," since the article con-

*See also No. 2709.

tained undissolved material. An article represented for parenteral use should be substantially free of any undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: February 28, 1949. Default decree of condemnation.

2701. Adulteration and misbranding of sodium phenobarbital tablets. U. S. v. 7 Cartons * * * (and 1 other seizure action). (F. D. C. Nos. 24896, 25087. Sample Nos. 15049–K, 22908–K.)

LIBELS FILED: June 23 and July 14, 1948, Northern District of Illinois and Middle District of Alabama.

ALLEGED SHIPMENT: On or about January 6 and 15, 1948, by Cole Laboratories, Inc., from Long Island City, N. Y.

PRODUCT: *Sodium phenobarbital tablets.* 7 cartons, each containing 24 bottles, at Hines, Ill., and 203 bottles at Montgomery, Ala. Examination showed that some of the bottles contained materially less than 1,000 entire tablets, together with broken and disintegrated tablets, and that some of the whole tablets contained less than 90 percent of the labeled amount of phenobarbital.

LABEL, IN PART: (Bottle) "1000 Hypodermic Tablets Each Tablet Contains 2 Grains (0.12 gm) Phenobarbital Sodium U. S. P. Distributed by Retort Pharmaceutical Co., Inc. Long Island City 1, New York."

NATURE OF CHARGE: Adulteration (portion), Section 501 (b), the article purported to be and was represented as "Sodium Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since a number of the whole tablets contained less than the declared amount of phenobarbital sodium.

Misbranding, Section 502 (a), the label statement "1000 * * * Tablets" was false and misleading since each bottle of the article contained materially fewer whole tablets than the declared number.

DISPOSITION: February 16, 1949. The Retort Pharmaceutical Co., Inc., having appeared as claimant and admitted the allegations of the libel, and the cases having been consolidated and removed to the Southern District of New York, judgment of condemnation was entered and the product was ordered released under bond for extraction of the phenobarbital, under the supervision of the Federal Security Agency.

2702. Adulteration of belladonna leaves. U. S. v. 3,642 Pounds * * *. (F. D. C. No. 24986. Sample No. 19167–K.)

LIBEL FILED: June 30, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: On or about February 6, 1948, by R. J. Prentiss & Co., Inc., from New York, N. Y.

PRODUCT: 3,642 pounds of *belladonna leaves* at Indianapolis, Ind. Examination showed that the product contained from 0.150 percent to 0.253 percent total alkaloids.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Belladonna Leaf," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since it contained less than 0.3 percent of the alkaloids of belladonna leaf.