DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2674. Adulteration of isotonic solution of sodium chloride and distilled water. U. S. v. 228 Bottles, etc. (F. D. C. No. 26254. Sample Nos. 46890–K, 46891–K.)

LIBEL FILED: January 3, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about November 16, 1948, by Readyflask, Inc., from Lakewood, Ohio.

PRODUCT: 228 bottles of *isotonic solution of sodium chloride* and 356 bottles of *distilled water* at Buffalo, N. Y. Each bottle contained 50 cc. The products were packaged in flasks of a type intended for the administration of injections.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" and "Water for Injection," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standards since they were contaminated with undissolved material.

DISPOSITION: February 1, 1949. Default decree of condemnation and destruction.

2675. Adulteration of water for injection. U. S. v. 988 Vials * * *. (F. D. C. No. 26280. Sample No. 7856–K.)

LIBEL FILED: January 17, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about October 23, 1948, from Decatur, Ill.

PRODUCT: 988 100-cc. vials of *water for injection* at Buffalo, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the product 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, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The product was adulterated while held for sale after shipment in interstate commerce.

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

2676. Adulteration of Hepafer Vitamin B_1. U. S. v. 1 Box * * *. (F. D. C. No. 26388. Sample No. 4849–K.)

LIBEL FILED: January 6, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about December 11, 1948, by Carlo Erba New York, Inc., from New York, N. Y.

PRODUCT: 1 box containing 72 ampuls of *Hepafer Vitamin B_1* at Springfield, Mass.

LABEL, IN PART: (Box) "Hepafer-Vitamin B_1 #2 * * * a sterile aqueous solution * * * Dosage and Administration: Intramuscularly"; (ampul) "Hepafer With Vitamin B_1 #2 * * * Intramuscular."

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, since the article purported to be and was represented as an aqueous solution intended for injection intramuscularly and was not suitable for such use. The

article was contaminated with undissolved material, whereas aqueous solutions intended for injection should be substantially free of undissolved material.

DISPOSITION: March 7, 1949. Default decree of condemnation and destruction.

2677. Adulteration of vitamin B complex. U. S. v. 88 Vials * * *. (F. D. C. No. 26386. Sample No. 48221–K.)

LIBEL FILED: January 5, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 17, 1948, by Carlo Erba New York, Inc., from New York, N. Y.

PRODUCT: 88 30-cc. vials of *vitamin B complex* at Philadelphia, Pa.

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 since the article was intended for parenteral administration and contained undissolved material, whereas an article intended for parenteral use should be substantially free of undissolved material.

DISPOSITION: February 8, 1949. Default decree of condemnation and destruction.

2678. Adulteration of Thiobismuth. U. S. v. 1 Box * * *. (F. D. C. No. 26383. Sample No. 11111–K.)

LIBEL FILED: On or about January 10, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about November 19, 1948, by Vincent Christina & Co., Inc., from New York, N. Y.

PRODUCT: 1 box containing 100 2-cc. ampuls of *Thiobismuth* at Jersey City, N. J.

LABEL, IN PART: (Box) "Thiobismuth Ampuls * * * Aqueous Solution of Sodium Bismuth Tartro-Amino Sulphone * * * For Intramuscular Use"; (ampul) "Thiobismuth For Intramuscular Use."

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 since the article was an aqueous solution intended for injection intramuscularly and was contaminated with undissolved material. Aqueous solutions intended for injection intramuscularly should be susbtantially free of undissolved material.

DISPOSITION: February 28, 1949. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration.

2679. Adulteration of Thiopentarson and Thiosol. U. S. v. 21 Vials, etc. (F. D. C. No. 26236. Sample Nos. 30796–K, 30799–K.)

LIBEL FILED: January 5, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about September 7, October 1, and November 5, 1948, from New York, N. Y.

PRODUCT: 21 100-cc. vials and 9 boxes, each box containing 24 2-cc. ampuls, and 17 boxes, each containing 12 2-cc. ampuls, of *Thiopentarson*, and 14 100-cc. vials of *Thiosol* at Los Angeles, Calif.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the articles fell below that which they purported and were represented to possess since they were for parenteral administration and contained undissolved material, whereas articles represented to be for parenteral use should be substantially free of undissolved material. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: February 8, 1949. Default decree of condemnation and destruction.