

Misbranding, Section 502 (a), the label statement "This product is sterile and non-pyrogenic" was false and misleading as applied to an article contaminated with living micro-organisms and pyrogen.

DISPOSITION: September 13, 1948. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for testing purposes.

2561. Adulteration of sodium iodide and sodium salicylate. U. S. v. 67 Ampuls * * *. (F. D. C. No. 23967. Sample Nos. 79517-H, 14603-K.)

LIBEL FILED: On November 24, 1947, Northern District of Illinois.

ALLEGED SHIPMENT: On or about July 18, 1947, by Bristol Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 67 ampuls of *sodium iodide and sodium salicylate* at Chicago, Ill.

LABEL, IN PART: "20 cc. size ampuls Sodium Iodide and Sodium Salicylate Sterile Solution for Intravenous Use."

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

DISPOSITION: February 3, 1948. Default decree of condemnation and destruction.

2562. Adulteration of sodium salicylate and iodide with colchicine. U. S. v. 4 Cartons * * *. (F. D. C. No. 25415. Sample No. 46005-K.)

LIBEL FILED: August 26, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about June 11, 1948, from Philadelphia, Pa.

PRODUCT: 4 cartons, each containing 12 20-cc ampuls, of *sodium salicylate and iodide with colchicine* at St. Louis, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sodium Salicylate and Iodide with Colchicine Ampuls," a drug the name of which is recognized in the National Formulary, 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: January 6, 1949. Default decree of condemnation and destruction.

2563. Adulteration of vitamin B complex with distilled water. U. S. v. 92 Packages * * *. (F. D. C. No. 25631. Sample No. 25868-K.)

LIBEL FILED: September 11, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about August 4, 1948, by Hyland Laboratories, from Los Angeles, Calif.

PRODUCT: 92 packages of *vitamin B complex with distilled water* at Minneapolis, Minn.

LABEL, IN PART: "10cc. B-Complex dried * * * with sterile diluent containing * * * Distilled Water 10cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the diluent 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 the diluent was contaminated with undissolved material.

DISPOSITION: January 6, 1949. Default decree of destruction.

2564. Adulteration of thiamine hydrochloride solution. U. S. v. 61 Vials, etc.
(F. D. C. No. 25419. Sample No. 19533-K.)

LIBEL FILED: September 1, 1948, Middle District of Tennessee.

ALLEGED SHIPMENT: On or about May 25, 1948, from Los Angeles, Calif.

PRODUCT: 61 30-cc. vials and 97 10-cc. vials of *thiamine hydrochloride solution* at Nashville, Tenn.

LABEL, IN PART: "Sterile solution Thiamine Hydrochloride * * * For Intramuscular or Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride 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 22, 1948. Default decree of destruction.

2565. Adulteration of vitamin B₁ and liver extract. U. S. v. 172 Vials, etc.
(F. D. C. No. 25507. Sample Nos. 30353-K, 30355-K, 30357-K.)

LIBEL FILED: August 31, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about February 19, March 11, and May 28, 1948, from Detroit, Mich.

PRODUCT: 172 30-cc. vials of *vitamin B₁* and 49 10-cc. vials of *liver extract* at Los Angeles, Calif.

LABEL, IN PART: "Vitamin B₁ (Thiamine Chloride) * * * Administer intravenously or intramuscularly" and "Liver Extract Injectable."

NATURE OF CHARGE: The products were adulterated while held for sale after shipment in interstate commerce under Section 501 (b), in that they purported to be and were represented respectively as "Thiamine Hydrochloride Injection" and "Liver Injection," drugs the names of which are recognized in the United States Pharmacopoeia, and their quality and purity fell below the official standards since the vitamin B₁ was contaminated with undissolved material and the *liver extract* was contaminated with heavy turbidity and precipitate.

DISPOSITION: October 20, 1948. Default decree of condemnation and destruction.

2566. Adulteration and misbranding of liver extract. U. S. v. 46 Vials * * *.
(F. D. C. No. 25630. Sample No. 30356-K.)

LIBEL FILED: September 9, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about June 30, 1948, by Sherman Laboratories, from Detroit, Mich.

PRODUCT: 46 vials of *liver extract* at Los Angeles, Calif.

LABEL, IN PART: "10 cc. Size Liver Extract Injectable 10 Units per cc. Sterile for intramuscular use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Liver Injection," the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell