

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Aminophylline 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.

DISPOSITION: November 12, 1948. Default decree of condemnation and destruction.

2617. Adulteration of calcium gluconate. U. S. v. 1,043 Ampuls * * *. (F. D. C. No. 25913. Sample Nos. 29360-K, 29361-K.)

LIBEL FILED: November 8, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about March 2 and September 29, 1948, by the Carroll Dunham Smith Pharmacal Co., from Kansas City, Mo.

PRODUCT: 1,043 10-cc. ampuls of *calcium gluconate* at Colorado Springs, Colo.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Calcium Gluconate 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.

DISPOSITION: December 23, 1948. Default decree of condemnation and destruction.

2618. Adulteration of thiamine hydrochloride. U. S. v. 26 Vials * * *. (F. D. C. No. 25765. Sample No. 10781-K.)

LIBEL FILED: September 21, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about April 21, 1948, from Newark, N. J.

PRODUCT: 26 30-cc. vials of *thiamine hydrochloride* at Brooklyn, N. Y.

LABEL, IN PART: "Sterile Multiple Dose Vial Thiamine Hydrochloride Vitamin B₁, * * * intramuscularly or intravenously."

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 15, 1948. Default decree of condemnation and destruction.

2619. Adulteration of solution of vitamin B complex. U. S. v. 17 Vials * * *. (F. D. C. No. 25752. Sample No. 30143-K.)

LIBEL FILED: September 16, 1948, District of Arizona.

ALLEGED SHIPMENT: On or about July 26, 1948, by the American Bio-Chemical Corp., from Los Angeles, Calif.

PRODUCT: 17 30-cc. vials of *solution of vitamin B complex* at Phoenix, Ariz.

LABEL, IN PART: "Sterile Solution Some Factors of Vitamin B Complex."

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 Some Factors of Vitamin B Complex * * * For intravenous or intramuscular use," since the article contained undissolved

material, whereas an article which is represented for intravenous use should be substantially free of any undissolved material.

DISPOSITION: November 19, 1948. Default decree of condemnation and destruction.

2620. Adulteration and misbranding of Congo red solution. U. S. v. 7 Cartons, etc. (and 1 other seizure action). (F. D. C. Nos. 25745, 25746. Sample Nos. 5179-K, 5372-K, 5373-K.)

LIBELS FILED: September 10, 1948, District of Massachusetts.

ALLEGED SHIPMENT: On or about April 11, May 28, and August 16, 1947, and May 4, 1948, by the Cosmos International Corp., from New York, N. Y.

PRODUCT: 27 cartons, each containing 5 5-cc. ampuls, and 13 cartons, each containing 5 10-cc. ampuls, of *Congo red solution* at West Roxbury and Boston, Mass. Analysis showed that the product contained not more than 0.7 percent of Congo red and that it was contaminated with undissolved material.

LABEL, IN PART: "Congo-Red (Cosmos) Isotonic Sterile Solution of Congo Red For Intravenous Injection Congo Red 1.2%."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.2 percent Congo red, since it contained less than the declared amount of Congo red, and its purity and quality fell below that which it purported and was represented to possess since it was represented to be for intravenous use and was contaminated with undissolved material, whereas an article for intravenous use should be substantially free of undissolved material.

Misbranding, Section 502 (a), the label statement "Congo Red 1.2%" was false and misleading as applied to a product containing less than the declared amount of Congo red; and its labeling was misleading since it failed to reveal the material fact, in the light of the representation that the product was for intravenous injection, that injections for intravenous use should not be used when they are contaminated with undissolved material.

DISPOSITION: November 15, 1948. Default decrees of condemnation and destruction.

2621. Adulteration and misbranding of Congo red solution. U. S. v. 11 Boxes
* * *. (F. D. C. No. 25782. Sample No. 10220-K.)

LIBEL FILED: September 27, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about April 14, 1948, by the Drug Products Co. Inc., from Passaic, N. J.

PRODUCT: 11 boxes, each containing 25 ampuls, of *Congo red solution* at Long Island City, N. Y. Analysis showed that the product contained not more than 0.83 percent of Congo red.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1 percent Congo red.

Misbranding, Section 502 (a), the label statement "Congo Red Solution 1% (W/V)" was false and misleading as applied to a product which contained less than the declared amount of Congo red.

DISPOSITION: November 10, 1948. Default decree of condemnation and destruction.