

On November 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1467. Adulteration of ampuls sodium salicylate. U. S. v. 575 Ampuls of Sodium Salicylate. Default decree of condemnation and destruction. (F. D. C. No. 14207. Sample No. 90342-F.)

On November 7, 1944, the United States attorney for the Eastern District of Arkansas filed a libel against 575 ampuls of sodium salicylate at Little Rock, Ark., alleging that the article had been shipped on or about September 21, 1944, from Brooklyn, N. Y., by the Adson-Intrasol Laboratories, Inc.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since the article was contaminated with undissolved material.

On December 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1468. Adulteration of boric acid. U. S. v. 13 Dozen Cartons of Boric Acid. Default decree of condemnation and destruction. (F. D. C. No. 14106. Sample Nos. 69509-F, 69518-F.)

On October 23, 1944, the United States attorney for the District of New Mexico filed a libel against 13 dozen cartons of boric acid at Santa Fe, N. Mex., alleging that the article had been shipped on or about May 11, 1943, and March 1, 1944, from Oklahoma City, Okla., by the Scotch-Tone Co.

The article was alleged to be adulterated in that alum had been substituted in whole or in part for boric acid, which the article was represented to be.

On December 1, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1469. Adulteration of iron cacodylate. U. S. v. 950 Ampuls of Iron Cacodylate. Default decree of condemnation and destruction. (F. D. C. No. 14041. Sample No. 64075-F.)

On October 16, 1944, the United States attorney for the Northern District of Georgia filed a libel against 950 ampuls, each containing 5 cc., of iron cacodylate at Atlanta, Ga., alleging that the article had been shipped on or about September 8, 1944, by the Adson-Intrasol Laboratories, Inc., from Brooklyn, N. Y. The article was labeled in part: "Iron cacodylate * * * intravenously."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, since it was contaminated with undissolved material.

On December 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1470. Adulteration and misbranding of Digifortis. U. S. v. 1,156 Bottles of Digifortis. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14085. Sample No. 78785-F.)

On November 2, 1944, the United States attorney for the Northern District of Illinois filed a libel against 1,156 bottles of Digifortis at Chicago, Ill., alleging that the article had been shipped on or about August 21, 1944, from Detroit, Mich., by Parke, Davis & Co. The article was labeled in part: "Digifortis * * * 125% Strength of Tincture Digitalis of International Standard."

The United States Pharmacopoeia specifies that 1 cc. of tincture of digitalis shall be equivalent to 1.0 U. S. P. digitalis unit; and it provides that tincture of digitalis which varies not more than 20 percent from the Pharmacopoeial requirement shall be considered to conform to that requirement. Examination of a sample of the article by the method prescribed in the Pharmacopoeia for tincture of digitalis showed that its potency was not less than 2.1 U. S. P. digitalis units per cubic centimeter.

The article was alleged to be adulterated in that it purported to be tincture of digitalis, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth in that compendium, and its difference in strength from the standard was not plainly stated on its label.

The article was alleged to be misbranded in that it was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug, i. e., tincture of digitalis. The article was alleged to be misbranded further (1) in that the statements in its labeling, (carton and bottle labels) "Original potency continued by the use of the International Standard and the lethal dose frog method of assay," and (circular

entitled "Digifortis Products") "The various Digifortis products provide the medical practitioner with Digitalis preparations of * * * uniform quality. They include Liquid Digifortis," were false and misleading since such statements created the impression that standardization of the article by use of a lethal dose frog method of assay enabled the maintenance of a definite clinical potency for humans, whereas standardization of the article by that method would not enable the maintenance of a definite clinical potency for humans; and (2) the statement on the label and carton of the article, "125% Strength of Tincture Digitalis of International Standard," was false and misleading since it created the impression that the potency of the article was 125 percent of that of tincture of digitalis as described in the United States Pharmacopoeia, which recognizes as a synonym for tincture of digitalis "Tinctura Digitalis P. I. [Protocol Internationale]," whereas the actual strength of the article was more than 200 percent of tincture of digitalis as described in the Pharmacopoeia.

On February 20, 1945, Parke, Davis and Co., claimant, having admitted the facts in the libel, judgment of condemnation was entered and the product was ordered released under bond for remanufacturing and relabeling under the supervision of the Food and Drug Administration.

1471. Adulteration of Narcosan, Narcosan-A, Elevin, Osmogen, and Sinesin. U. S. v. 6 Boxes of Narcosan, 11 Boxes of Narcosan-A, 2 Boxes of Elevin, 3 Boxes of Osmogen and 3 Boxes of Sinesin. Default decree of condemnation and destruction. (F. D. C. No. 13428. Sample Nos. 53766-F, 53769-F, 53771-F, 53773-F, 53776-F, 53777-F.)

On August 25, 1944, the United States attorney for the Southern District of California filed a libel against 6 boxes of Narcosan, 11 boxes of Narcosan-A, 2 boxes of Elevin, 3 boxes of Osmogen, and 2 boxes of Sinesin, each box containing 12 ampuls (1-cc. size), and against 1 box containing 30 cc. of Sinesin, at Los Angeles, Calif., alleging that the articles had been shipped by the Lipoidal Laboratories, from New York, N. Y. It was also alleged that shipments of the Narcosan and Narcosan-A were made on or about June 28 and October 15, 1943, respectively, and that the shipment dates of the other articles were unknown.

Examination showed that the articles, each of which bore directions for intramuscular administration, were contaminated with living micro-organisms and therefore unsuitable for intramuscular administration.

The articles were alleged to be adulterated in that their purity and quality fell below that which they purported and were represented to possess.

On September 19, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1472. Adulteration of triple distilled water. U. S. v. 270 Ampuls and 1,990 Ampuls of Triple Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 14010. Sample No. 64073-F.)

On or about October 12, 1944, the United States attorney for the Northern District of Georgia filed a libel against 270 5-cc. ampuls and 1,990 10-cc. ampuls of triple distilled water at Atlanta, Ga., alleging that the article had been shipped on or about August 10, 1944, by the American Medical Specialties Co., Inc., from New York, N. Y.

The article was alleged to be adulterated in that it 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, but its quality and purity fell below the official standard since the compendium provides that water for injection is a clear liquid, whereas the article was not a clear liquid but contained suspended material.

On March 16, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1473. Adulteration of triple distilled water. U. S. v. 350 Ampuls of Triple Distilled Water. Default decree of condemnation. Product ordered delivered to the Food and Drug Administration. (F. D. C. No. 13819. Sample No. 78856-F.)

On September 26, 1944, the United States attorney for the Eastern District of Michigan filed a libel against 350 ampuls, 10-cc. size, of the above-named product at Detroit, Mich., alleging that the article had been shipped on or about July 15, 1944, by the Torigian Laboratories, Inc., Queens Village, N. Y. The article was labeled in part: "Triple Distilled Water for Injection."

Examination showed that the article contained pyrogens and was contaminated with undissolved material.