

2738. Adulteration of sodium sulfadiazine solution. U. S. v. 125 Ampuls * * * .
(F. D. C. No. 26019. Sample No. 1319-K.)

LIBEL FILED: On or about November 16, 1948, Northern District of Georgia.

ALLEGED SHIPMENT: Between the approximate dates of April 2, 1947, and March 31, 1948, from Indianapolis, Ind.

PRODUCT: 125 20-cc. ampuls of *sodium sulfadiazine solution* at Atlanta, Ga.

LABEL, IN PART: "Ampul Solution Sodium Sulfadiazine 25% W/V * * *
Use only intravenously."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it was represented to possess since it was represented for intravenous use and was contaminated with undissolved material, whereas an article represented for intravenous use should be substantially free of any undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

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

2739. Adulteration of Bromsulphalein. U. S. v. 20 Boxes * * * . (F. D. C. No. 26901. Sample No. 57795-K.)

LIBEL FILED: April 4, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about December 28, 1948, by Hynson, Westcott & Dunning, Inc., from Baltimore, Md.

PRODUCT: 20 boxes of *Bromsulphalein* at Wilmington, Calif.

LABEL, IN PART: (Box) "Ten Ampules 3-cc. Size Bromsulphalein (H. W. & D. Brand of Sulfobromophthalein Sodium U. S. P. * * *) Sterile 5% Aqueous Solution Lot No. 335."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as a drug, "Sulfobromophthalein Sodium Injection," 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: May 16, 1949. Default decree of condemnation and destruction.

2740. Adulteration and misbranding of estrogenic substance. U. S. v. 91 Vials * * * . (F. D. C. No. 26555. Sample No. 15268-K.)

LIBEL FILED: March 7, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about November 11, 1948, by the Estro Chemical Co., from New York, N. Y.

PRODUCT: 91 10-cc. vials of *estrogenic substance* at Chicago, Ill.

LABEL, IN PART: "Aqua-Gyne Aqueous Estrogenic Substance."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 97 percent of the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc * * * contains * * * (Estrogenic Substances predominantly Estrone) * * * (Ketosteroids as Estrone, approximately 97% by potency) * * * equivalent to 20,000 I. U. (assayed in terms of Estrone)" was false and misleading as applied to an article which contained materially less than 97 percent of

the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

DISPOSITION: May 24, 1949. Default decree of condemnation and destruction.

2741. Adulteration and misbranding of cotton swabs. U. S. v. 142 Cartons * * *
(F. D. C. No. 26447. Sample No. 4716-K.)

LIBEL FILED: January 31, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about November 10, 1948, by Steri-Swab, Inc., from Jamaica, Long Island, N. Y.

PRODUCT: 142 cartons of *cotton swabs* at Worcester, Mass.

LABEL, IN PART: "200 Uni-Swabs * * * The Only Sterile Swabs * * * Always remains sterile."

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 it was not sterile but was contaminated with living organisms.

Misbranding, Section 502 (a), the label statements "The Only Sterile Swabs" and "Always remains sterile" were false and misleading as applied to a product that was not sterile.

DISPOSITION: April 4, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2742. Misbranding of Nucone. U. S. v. Alva Irvin Cotterman (Nuco Products Co.).
Plea of guilty. Fine, \$100. (F. D. C. No. 25628. Sample Nos. 44432-K, 44433-K.)

INFORMATION FILED: March 11, 1949, Southern District of Ohio, against Alva Irvin Cotterman, trading as the Nuco Products Co., West Union, Ohio.

ALLEGED SHIPMENT: On or about August 10, 1948, from the State of Ohio into the State of Kentucky.

LABEL, IN PART: "Nucone * * * Contents: Oil of Sassafras, Smilax, Sweet Burch, Methyl-Salicylate."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, which included a form letter beginning with the words "A Letter from the original maker: Nucone is Registered," a form letter beginning with the words "A Letter from the original Maker: Nucone is a Medicine," and circulars entitled "Read What Users Have To Say About Nucone" and "Almost Unbelievable Letters," were false and misleading. The statements represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of neuritis, rheumatism, arthritis, neuralgia, sinus trouble, and all muscular conditions; that it would be efficacious in the treatment of conditions affecting all organs of the body; and that it was made under the provisions of the Pure Food and Drug Act and was registered under the provisions of that act. The article would not be efficacious for the purposes represented, and it was not made, nor was it registered, under the provisions of the Pure Food and Drug Act.

DISPOSITION: May 13, 1949. A plea of guilty having been entered, the court imposed a fine of \$100.

*See also Nos. 2731-2733, 2740, 2741.