DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2822. Misbranding of estrogenic substance. U. S. v. 197 Vials * * *. (F. D. C. No. 27331. Sample No. 48470-K.)

LIBEL FILED: June 16, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 28, 1949, by the Sonoral Laboratories, from New York, N. Y.

PRODUCT: 197 unlabeled vials of *estrogenic substance* at Sellersville, Pa. The product was packaged in cartons of 24 vials each. No agreement as to labeling existed between the shipper and the dealer.

LABEL, IN PART: (Carton) "10 cc Size * * * Vial Estrone 10% Diol-Sex Suspension Estradiol 20,000 I. U. per cc."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Estradiol 20,000 I. U. per cc." appearing on the cartons was false and misleading, since there is no International Unit of estradiol activity and the statement created the misleading impression that there is some recognized relationship between the potencies of alpha-estradiol and estrone, an estrogen for which there is an International Unit, when in fact there is not; Section 502 (b) (1), the article failed to bear a label on the vials containing the name and place of business of the manufacturer, packer, or distributor: Section 502 (b) (2), it failed to bear a label on the vials containing an accurate statement of the quantity of the contents; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and the vials containing the article failed to bear a label containing the common or usual name of each active ingredient.

DISPOSITION: July 27, 1949. Default decree of condemnation and destruction.

2823. Misbranding of Sercaps. U. S. v. 97 Bottles, etc. (F. D. C. No. 27216. Sample No. 42350-K.)

LIBEL FILED: June 10, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: During November 1948, by Sercaps, Inc., from Detroit, Mich.

PRODUCT: 40 50-tablet bottles, 57 20-tablet bottles, and 79 packets of 8 tablets each, of *Sercaps* at Chicago, Ill., together with a number of leaflets entitled "Sercaps" and display cards entitled "Relief For Piles." Examination showed that the product consisted essentially of coated tablets containing sulfur, potassium tartrate, and plant material.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since the article was not effective in the treatment of the conditions suggested or implied. The statements represented and suggested that the article would be efficacious for the relief of piles; that it would be efficacious in the treatment of the discomfort due to blind, bleeding, and itching hemorrhoids, both internal and external; and that it would ease the pain of piles, allay pile nervousness, and tend to relieve sore and swollen tissue.

DISPOSITION: July 27, 1949. Default decree of condemnation and destruction.

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*See also Nos. 2812, 2817, 2818, 2820, 2821.