

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF
FALSE AND MISLEADING CLAIMS****DRUGS FOR HUMAN USE***

2634. Misbranding of Estromone. U. S. v. 42 Vials * * * (and 1 other seizure action). (F. D. C. Nos. 16027, 16378. Sample Nos. 16233-H, 31429-H, 31442-H, 31443-H.)

LIBELS FILED: May 23 and June 16, 1945, Northern District of Illinois and Southern District of California.

ALLEGED SHIPMENT: Between the approximate dates of January 1 and May 10, 1945, by Endo Products, Inc., from Richmond Hill, N. Y.

PRODUCT: *Estromone*. 42 vials at Chicago, Ill., and 128 vials at Los Angeles, Calif. The product was contained in 10-cc. and 25-cc. vials. Examination showed that it was an oil solution containing estrogenic substances consisting essentially of estradiol, with an insignificant amount, if any, of estrone.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article "Estrogenic Substance Derived from Equine Urine," "Estrogenic Substance derived from pregnant mares' and stallions' urine," and "from natural sources" were false and misleading since the estrogenic material present in the article did not consist of estrogenic substances as derived from pregnant mares' and stallions' urine or from equine urine.

Further misbranding, Section 502 (e) (2), the article in the California lot was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since the designation "Estrogens" appearing on some of the packages is not the specific name of any particular substance but is a generic name for a class of substances; and the statement "Estrogenic Substance derived from pregnant mares' and stallions' urine," or "Estrogenic Substance Derived from Equine Urine," appearing on the remainder of the packages, is not the common or usual name of the active ingredients of the article.

DISPOSITION: Endo Products, Inc., appeared as claimant, and in accordance with its request, the cases were consolidated and transferred to the Southern District of New York. On October 19, 1948, the claimant having admitted the allegations of the libels, judgment of condemnation was entered and the product was ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

2635. Misbranding of Dr. E. L. Welbourn's Elixir. U. S. v. 77 Cartons * * * (F. D. C. No. 24930. Sample No. 19440-K.)

LIBEL FILED: July 6, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about August 29, 1947, and February 10, 1948, by Dr. E. L. Welbourn Medicine Co., from Union City, Ind.

PRODUCT: 39 6-ounce cartons and 38 smaller cartons, some containing a circular entitled "Dr. E. L. Welbourn's Elixir" and each containing 1 bottle of *Dr. E. L. Welbourn's Elixir*, at Dayton, Ohio. Examination showed that the product consisted essentially of water, alcohol, potassium bicarbonate, extracts of plant drugs including a laxative plant drug, sugar, and flavoring materials.

*See also Nos. 2601, 2602, 2604-2606, 2620-2633, 2646.