

**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.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the circular were false and misleading since they represented and suggested that the article was effective in the treatment of the diseases, symptoms, and conditions stated and implied, whereas the article was not effective for such purposes: "Quickly relieves the disturbing distress of Belly-Ache caused by upset stomach—colic—overindulgence—nervous indigestion * * * This medicine gives prompt and speedy relief for 'Belly-Ache' caused by over-eating—nervous indigestion—gas on the stomach—upset stomach—colic. Dr. E. L. Welbourn's Elixir gives speedy relief and checks minor stomach and bowel complaints, such as vomiting and diarrhoea and is especially useful in relieving the distress caused by eating foods and liquids that upset the digestion. Very effective in relieving distress of summer complaint and intestinal flu. Also—it speedily relieves colic and upset stomachs of children. Children of all ages frequently suffer from upset stomachs. Give them this Elixir and relieve this distress. It is also an invaluable aid in relieving the distress in children caused by summer complaint and teething. This Elixir also aids in improving the digestion * * *. It is also used as a tonic and as an aid in improving the digestive processes of elderly people—also acts quickly to relieve various digestive upsets peculiar to elderly people. * * * fast acting 'Belly-Ache' reliever * * * for that sudden upset stomach or 'Belly-Ache' * * * Children cry for more * * * For simple diarrhoea, Looseness of the bowels—Pain or Gripping * * * For indigestion * * * will start digestion * * * For colic * * * For upset stomach caused by teething * * * rub the Elixir on the gums to ease the discomfort."

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

✓ 2636. Misbranding of iron and yeast tablets, and Brother Tom's Medicine. U. S. v. 54 Dozen Envelopes, etc. (F. D. C. Nos. 25461, 25462. Sample Nos. 28400-K, 29231-K.)

LABEL FILED: August 27, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about March 20, 21, 29, and 30, May 11, and June 28, 1948, by the Brother Tom's Medicine Co., from Los Angeles, Calif.

PRODUCT: 54 dozen envelopes of *iron and yeast tablets* and 54 dozen 12-ounce bottles of *Brother Tom's Medicine* at Denver, Colo. Each bottle of the medicine had one envelope of tablets attached to it by transparent adhesive tape. In addition to the tablets, each envelope contained a circular entitled "Marginal Anemia The 24 Hour Thief."

LABEL, IN PART: (Tablets) "Four Tablets Contain Iron 75 Mg. (Ferrous Sulf. Exsic. 3.9 Gr.) Yeast 12 Gr. (Primary Dried U. S. P.) B₁ (Thiamin) 1.8 mg. with excipients and fillers."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular were false and misleading. These statements suggested and implied that the tablets would preserve a lady's beauty and prevent her face from growing pale when her freshness was lagging and her energy was low; that they would remedy puny, weak, red blood cells, enabling them to send full energy into one's system; that they would build energy, would correct tired, listless, pale conditions, and would cause the red cells to release energy to the body; and that they would favorably affect puny, faded cells, enabling them to release needed energy and cause one to look and feel one's best. The tablets would not be effective for such purposes..