

LABEL, IN PART: "25 cc. Sterile Solution Estrogenic Material in Oil 30,000 [or "10,000," or "50,000"] Int. Units per cc."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "This Estrogenic Material Contains Estrodiol, Estrone and other Estrogenic factors of Pregnant Mares Urine," was false and misleading as applied to the article.

DISPOSITION: October 9, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1794. Misbranding of Estrol. U. S. v. 78 Cartons of Estrol. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No 16419. Sample No. 16256-H.)

LABEL FILED: June 13, 1945, Northern District of Illinois.

ALLEGED SHIPMENT: On or about March 26, 1945, from New York, N. Y., by the C. F. Kirk Co.

PRODUCT: 78 cartons, each containing 1 vial, of *Estrol* at Chicago, Ill. Examination showed that the product was an oil solution containing estrogenic substances consisting essentially of estradiol, with no significant proportion of estrone, which is the principal estrogenic hormone occurring in natural sources such as equine urine.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the vial label, "Natural Estrogen obtained from Equine Urine," and on the carton label, "Estrogenic Hormones obtained from Equine Urine," were false and misleading since the estrogenic material present in the article did not consist of natural estrogenic substance as derived from equine urine.

DISPOSITION: July 2, 1945. The Gamma Pharmaceutical Co., Chicago, Ill., claimant, having admitted the facts of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1795. Misbranding of estrogen in peanut oil. U. S. v. 53 Vials of Estrogen in Peanut Oil. Default decree of condemnation and destruction. (F. D. C. No. 16099. Sample No. 16216-H.)

LABEL FILED: May 23, 1945, Northern District of Illinois.

ALLEGED SHIPMENT: On or about March 1, 1945, by the Pro-Medico Laboratories, Inc., from Brooklyn, N. Y.

PRODUCT: 53 vials of *estrogen in peanut oil*, at Chicago, Ill. Examination showed that the product was an oil solution of estrogenic material consisting essentially of estradiol, with no significant proportion of estrone, the principal estrogenic hormone in prenatal mares' urine. There were no labels upon the immediate containers, the glass vials, as they were shipped, and there was no agreement between the shipper and the consignee with respect to labeling the vials.

LABEL, IN PART: (Cartons) Gynestrin 30 cc size * * * A sterile oil solution of di-hydro derivatives of estrogenic substances and estrogene substance derived from equine urine."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement on the carton, "A sterile oil solution of di-hydro derivatives of estrogenic substances and estrogene substance derived from equine urine," was false and misleading since the estrogenic material present did not consist of estrogenic material as extracted from equine urine; Section 502 (b) (1), the product was a drug in package form and the individual vials failed to bear a label stating the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the labels failed to bear an accurate statement of the quantity of the contents of the vials in terms of measure; and, Section 502 (e), the article was a drug fabricated from two or more ingredients, but its label failed to bear the common or usual name of each active ingredient, since the carton label did not bear the name "estradiol," which is the common or usual name of the principal active ingredient of the article, and the vials had no label whatever.

DISPOSITION: September 14, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1796. Misbranding of infrared bulbs. U. S. v. 11 Packages of Infrared Bulbs, and 11 circulars. Default decree of condemnation and destruction. (F. D. C. No. 16476. Sample No. 12994-H.)

LABEL FILED: June 20, 1945, Southern District of Ohio.