

1658. Adulteration and misbranding of Estrovin in Oil. U. S. v. 311 Boxes of Estrovin in Oil. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 15792. Sample No. 6202-H.)

LIBEL FILED: On or about April 13, 1945, District of New Jersey.

ALLEGED SHIPMENT: On or about December 7, 1944, by the Adson-Intrasol Laboratories, Inc., from Brooklyn, N. Y.

PRODUCT: 311 boxes, each containing 25 ampuls, of *Estrovin in Oil*, at Newark, N. J. Examination showed that the product contained estradiol with a very small proportion of estrone.

LABEL, IN PART: (Box) "Estrovin (Estrogenic Hormones Substance) In Oil * * * 1 cc. contains 10,000 I. U. of Estrogenic Hormones Substance, obtained from Equine Urine."

NATURE OF CHARGE: Adulteration, Section 501 (d), an oil solution of estrogenic material consisting essentially of estradiol had been substituted in whole or in part for an oil solution of the estrogenic hormones substance obtained from equine urine.

Misbranding, Section 502 (a), the label statement, "1 cc. contains 10,000 I. U. of Estrogenic Hormones Substance, obtained from Equine Urine," was misleading since the estrogenic hormones substance contained in the article did not consist of estrogenic hormones naturally occurring in equine urine.

DISPOSITION: July 13, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable institution, after destruction of the labels under the supervision of the Food and Drug Administration.

1659. Adulteration of Estrinol. U. S. v. 96 Vials of Estrinol. Decree of condemnation. Product ordered released upon payment of costs. (F. D. C. No. 15880. Sample No. 4447-H.)

LIBEL FILED: April 6, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 16, 1945, by the Bellevue Laboratories, Inc., from New York, N. Y.

PRODUCT: 96 30-cc. vials of Estrinol at Philadelphia, Pa. Examination showed that the estrogenic material present consisted essentially of estradiol with no significant proportion of estrone.

LABEL, IN PART: "30 cc. + Estrinol a purified preparation in sesame oil. Each c. c. is equivalent to 10000 I. U. of natural occurring estrogenic substances from pregnant mare urine containing principally estrone. Chlorbutanol 0.5% (Chloroform derivative)."

NATURE OF CHARGE: Adulteration, Section 501 (d), a preparation containing estrogenic material including little or no estrone had been substituted in whole or in part for a preparation of natural occurring estrogenic substances from pregnant mare urine containing, principally, estrone.

DISPOSITION: July 11, 1945. Bellevue Laboratories, Inc., having appeared as claimant, judgment of condemnation was entered and the product was ordered released, upon the payment of costs, to be relabeled under the supervision of the Food and Drug Administration.

1660. Adulteration of Hyposols Liver Solution. U. S. v. 20 Vials of Hyposols Liver Solution. Default decree of forfeiture and destruction. (F. D. C. No. 15900. Sample No. 11228-H.)

LIBEL FILED: April 12, 1945, District of Vermont.

ALLEGED SHIPMENT: On or about January 15, 1945, by the Drug Products Co., from Long Island City, N. Y.

PRODUCT: 20 vials of *Hyposols Liver Solution* at Windsor, Vt. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "10 cc. Size Multiple Dose Vial Hyposols Liver Solution U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be liver injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.