

ern District of Missouri filed libels against the following quantities of the above-named product: 52 vials at Philadelphia, Pa., 57 vials at Irvington, N. J., and 168 bottles at St. Louis, Mo., alleging that the article had been shipped between the approximate dates of November 8, 1944, and January 18, 1945, by the Premo Pharmaceutical Laboratories, Inc., from New York, N. Y. The article was labeled in part: "1 Fld. Oz. Premo Vasodrine Solution of Epinephrine Hydrochloride U. S. P. 1-1000."

The United States Pharmacopoeia provides that solution of epinephrine hydrochloride has a potency equivalent to a solution containing 1 gram of U. S. P. Epinephrine Reference Standard in each 1,000 cc. Examination showed that the article had an activity of from 27 to 45 percent of that claimed upon its label and required by the Pharmacopoeia.

The article was alleged to be adulterated in that it was represented as a drug the name of which is recognized in an official compendium, the United States Pharmacopoeia XII, and its strength differed from the standard set forth therein.

It was alleged to be misbranded in that the statement on its label, "Solution of Epinephrine Hydrochloride U. S. P. 1-1000," was false and misleading as applied to the article.

Between February 13 and April 2, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

**1509. Adulteration and misbranding of estrogenic hormones in oil. U. S. v. 3 Bottles of Estrogenic Hormones. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14868. Sample No. 78195-F.)**

On December 26, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 3 bottles containing a total of approximately 5,300 cc. of estrogenic hormones at Philadelphia, Pa., alleging that the article had been shipped on or about October 4 and 16, 1944, from Chicago, Ill., by the W. F. Straub and Co.

Examination disclosed that the potency of the article was equivalent to not more than 12,000 International Units of estrone per cubic centimeter.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, 20,000 International Units of estrogenic ovarian follicular hormones.

The article was alleged to be misbranded in that the statements on its label, "Whole Natural Estrogenic Hormones From Pregnant Mare's Urine Consisting Mainly of Estrone and Estradiol in Sesame Oil 20,000 IU/CC," were false and misleading since the potency of the article was materially less than was represented.

On March 2, 1945, W. F. Straub and Co., claimant, having admitted the allegations 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.

**1510. Adulteration and misbranding of estrogenic hormone injection. U. S. v. 326 Vials of Estrogenic Hormone Injection. Default decree of condemnation and destruction. (F. D. C. No. 15314. Sample No. 85315-F.)**

On February 24, 1945, the United States attorney for the Eastern District of Pennsylvania filed a libel against 326 vials of estrogenic hormone injection at Philadelphia, Pa. It was alleged in the libel that the article had been repackaged by the consignee at Philadelphia, Pa., from bulk material contained in 5 1-liter bottles which had been shipped to it by Halfdan Hebo, from New York, N. Y., on or about May 20, 1944.

The article in the 1-liter bottles was labeled in part: "Biologically tested Estrogenic Substance in Propylene Glycol, 10,000 I. U. per ml." The article in the vials was labeled in part: "Injection Estrogenic Hormone \* \* \* Each cc. contains Estrogenic Hormone 10,000 I. U., obtained from pregnant mares' urine, consisting principally of estrone and estradiol, with Chlorobutanol \* \* \* 1.5% in sterile propylene glycol."

Examination of a sample taken from the repackaged material showed that the article contained estrogenic steroids consisting of compounds including little or no estrone, together with the inert substance cholesterol.

The article was alleged to be adulterated in that a substance containing estrogenic material including little or no estrone and the inert compound cholesterol

had been substituted in whole or in part for natural estrogenic hormones in approximately the proportions in which they are present in the animal system and not broken down to estradiol.

The article was alleged to be misbranded in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

On April 3, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1511. Adulteration and misbranding of estrogenic hormones in oil. U. S. v. 9,500 Cubic Centimeters of Estrogenic Hormones in Oil. Default decree of condemnation and destruction. (F. D. C. No. 15270. Sample No. 82813-F.)**

On February 14, 1945, the United States attorney for the District of New Jersey filed a libel against 9,500 cc. of the above-named product at Bloomfield, N. J., alleging that the article had been delivered on or about April 12, 1944, by the Unified Laboratories, Inc., in New York, N. Y., to an agent of the Lehn and Fink Products Corp., and was transported by that agent on the same date to Bloomfield, N. J. The article was invoiced as "Sesame Oil containing 50,000 International Units of Estrogens (Natural) per cubic centimeter." The only labels which the article bore when it was transported in interstate commerce were stickers bearing various numbers indicating in cubic centimeters the quantity of the contents at various levels of the bottle.

Examination of a sample showed that the article contained an insignificant proportion, if any, of estrone.

It was alleged to be adulterated in that substances other than estrogens derived from natural sources had been substituted in whole or in part for estrogens (natural). The article was alleged to be misbranded (1) in that it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and (2) in that its label failed to bear the common or usual name of its active ingredients.

On March 26, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**1512. Adulteration and misbranding of estrogenic substance in sesame oil. U. S. v. 2 Filled Bottles and One Partly Filled Bottle of Estrogenic Substance in Sesame Oil. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 15268. Sample No. 85231-F.)**

On February 12, 1945, the United States attorney for the Eastern District of Pennsylvania filed a libel against 2 filled bottles and one partly filled bottle of the above-named product at Philadelphia, Pa., alleging that the article had been shipped on or about November 27, 1944, from Maspeth, N. Y., by the Hema Drug Co., Inc. The article was invoiced as "Natural Estrogenic Hormone in Sesame Oil."

Examination of a sample disclosed that the article contained an estrus-producing hormone, including little, if any, estrone.

It was alleged to be adulterated in that substances other than natural estrogenic hormones in sesame oil had been substituted in whole or in part for natural estrogenic hormones in sesame oil. It was alleged to be misbranded in that its label failed to bear the common or usual names of its active ingredients.

On April 24, 1945, the Hema Drug Co., Inc., having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

**1513. Adulteration of lubricating jelly. U. S. v. 23½ Dozen Tubes of Lubricating Jelly. Default decree of condemnation and destruction. (F. D. C. No. 15164. Sample No. 74315-F.)**

On January 25, 1945, the United States attorney for the Southern District of California filed a libel against 23½ dozen tubes of lubricating jelly at Los Angeles, Calif., alleging that the article had been shipped on or about November 3, 1944, by the McNeil Laboratories, from Philadelphia, Pa. The article was labeled in part: "Lubricant A Sterile \* \* \* Jelly."

Examination showed that the article was not sterile but was contaminated with living micro-organisms.

It was alleged to be adulterated in that its purity and quality fell below that which it purported or was represented to possess.

On March 13, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.