

DISPOSITION: September 28, 1948. Default decree of condemnation and destruction.

2523. Adulteration and misbranding of estrogenic hormone. U. S. v. 1 Bottle * * * (F. D. C. No. 24328. Sample No. 18025-K.)

LIBEL FILED: February 10, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: On or about November 18, 1947, by Hema Drug Co., Inc., from Maspeth, N. Y.

PRODUCT: 1 bottle containing 3 liters of *estrogenic hormone* at Indianapolis, Ind. Examination showed that each cubic centimeter of the article contained 0.78 milligram of ketones calculated as estrone.

LABEL, IN PART: "Whole Natural Estrogenic Hormone in Propylene Glyco."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, i. e., "Whole Natural Estrogenic Hormone * * * consisting of estrone with small amounts of auxiliary hormones, each cc equivalent to 20,000 international unit of estrone. Minimum ketone content 90-95%."

Misbranding, Section 502 (a), the above-quoted label statement was false and misleading, since the article did not have the composition represented and implied thereby.

DISPOSITION: November 1, 1948. Default decree of forfeiture and destruction.

2524. Adulteration and misbranding of Aquadiol. U. S. v. 23 Vials * * * (F. D. C. No. 25124. Sample No. 255-K.)

LIBEL FILED: July 27, 1948, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 17, 1948, by the National Drug Co., from Atlanta, Ga.

PRODUCT: 23 vials of *Aquadiol* at Philadelphia, Pa. Examination showed that the product contained less than 0.13 milligram of alpha estradiol per cubic centimeter.

LABEL, IN PART: (Vial) "25 cc. Aquadiol * * * Estrogenic Hormone containing per cc. 0.22 mg. alpha Estradiol."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., 0.22 milligram of alpha estradiol per cubic centimeter.

Misbranding, Section 502 (a), the label statement "per cc. 0.22 mg. alpha estradiol" was false and misleading.

DISPOSITION: September 14, 1948. Default decree of condemnation and destruction.

2525. Adulteration of phenobarbital tablets. U. S. v. 14 Drums * * * (F. D. C. No. 24846. Sample Nos. 18498-K, 18499-K, 18787-K, 18788-K.)

LIBEL FILED: May 21, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about February 27 and March 12, 1948, by Clark-Babbitt Pharmaceutical Labs., Inc., from Boston, Mass.

PRODUCT: *Phenobarbital tablets*. 8 drums containing a total of 400,000 tablets and 6 drums containing a total of about 388,525 tablets at Gallipolis, Ohio.

LABEL, IN PART: "C. T. Phenobarbital 1½ gr."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the official standard, since a portion of the tablets contained less than the declared amount of phenobarbital and the remainder of the tablets contained more than the declared amount of phenobarbital. (The tablets in the 8-drum lot contained less than 80 percent of the declared amount of phenobarbital; the tablets in 1 drum of the 6-drum lot contained not more than 92 percent; and those in the remaining 5 drums contained more than 109 percent of the labeled amount of phenobarbital. The Pharmacopoeia requires that *phenobarbital tablets* contain not less than 94 percent, and not more than 106 percent, of the labeled amount of phenobarbital.)

DISPOSITION: July 29, 1948. Default decree of destruction.