

**3527. Adulteration and misbranding of pentobarbital sodium (powder). U. S. v. 4 Canisters \* \* \*. (F. D. C. No. 30844. Sample No. 86313-K.)**

**LABEL FILED:** February 20, 1951, Southern District of California.

**ALLEGED SHIPMENT:** On or about August 25, 1950, by B. L. Lemke & Co., Inc., from Lodi, N. J.

**PRODUCT:** 4 5-pound canisters of *pentobarbital sodium* (powder) at Los Angeles, Calif. Examination showed that the product contained not more than 97.5% pentobarbital sodium, calculated on the anhydrous basis, whereas the United States Pharmacopeia provides that the drug contain not less than 98.5% of pentobarbital sodium so calculated.

**LABEL, IN PART:** "Pentobarbital Sodium U. S. P. XIII."

**NATURE OF CHARGE:** Adulteration, Section 501 (b), the article purported to be and was represented as "Pentobarbital Sodium," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality and purity fell below, the official standard since the article contained a lesser proportion of pentobarbital sodium and a greater proportion of impurities than permitted by the official compendium.

Misbranding, Section 502 (a), the label statement "Pentobarbital Sodium U. S. P. XIII" was false and misleading as applied to an article which did not conform to the requirements of the U. S. P. XIII.

**DISPOSITION:** September 6, 1951. B. L. Lemke & Co., Inc., claimant having entered into a stipulation with the Government agreeing to the entry of a decree providing for the destruction of the product, judgment was entered ordering that the product be destroyed.

**3528. Adulteration and misbranding of Cogenat (conjugated estrogens). U. S. v. 9,200 Tablets, etc. (F. D. C. No. 31336. Sample Nos. 17456-L, 17457-L.)**

**LABEL FILED:** July 10, 1951, Southern District of California.

**ALLEGED SHIPMENT:** On or about September 6, 1950, and other unknown dates, by the National Drug Co., from Philadelphia, Pa.

**PRODUCT:** *Cogenat* (conjugated estrogens). 9,200 tablets in 74 bottles and 11,700 tablets in 90 bottles at Los Angeles, Calif.

Analysis showed that the 74-bottle lot contained a total amount of estrogenic steroids calculated as 0.65 mg. of sodium estrone sulfate per tablet and that the 90-bottle lot contained a total amount of estrogenic steroids calculated as 0.35 mg. of sodium estrone sulfate per tablet.

**LABEL, IN PART:** "Cogenat \* \* \* Conjugated Estrogens."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article in the two lots differed from that which it was represented to possess, namely, 1.25 mg. and 0.625 mg., respectively, of conjugated estrogens (equine) per tablet expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statements "Each tablet contains: Conjugated Estrogens (Equine) 1.25 mg. [or "0.625 mg."] expressed as Sodium Estrone Sulfate" were false and misleading as applied to an article which contained less than the stated amounts, respectively, per tablet of the total estrogenic steroids calculated as sodium estrone sulfate.

**DISPOSITION:** August 2, 1951. Default decree of condemnation and destruction.