

packaged tablets were not genuine 1.25 mg. Premarin tablets and did not contain conjugated water-soluble estrogens.

DISPOSITION: May 16, 1952. A plea of nolo contendere having been entered, the court imposed a fine of \$500.

**3831. Adulteration and misbranding of stilbestrol tablets. U. S. v. 233,700 Tablets \* \* \*. (F. D. C. No. 32985. Sample No. 49041-L.)**

LIBEL FILED: March 27, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 21, 1952, by Nysco Laboratories, Inc., from Newark, N. J.

PRODUCT: 233,700 *stilbestrol tablets* at Long Island City, N. Y.

LABEL, IN PART: (Tin) "Stilbestrol Tablets 1.0 Mg. \* \* \* Warning: This is an extremely dangerous and toxic drug. Improper use may result in severe and even fatal injury \* \* \* Empire Chemical Co., Inc. New Brunswick, New Jersey."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Diethylstilbestrol Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard. (The standard provides that diethylstilbestrol tablets contain not less than 90 percent and not more than 110 percent of the labeled amount of diethylstilbestrol. Analysis showed that the article contained from 122 to 125 percent of the labeled amount.)

Misbranding, Section 502 (a), the label statement "Stilbestrol Tablets 1.0 Mg." was false and misleading as applied to the article, which contained from 1.22 to 1.25 mg. of diethylstilbestrol per tablet.

DISPOSITION: October 29, 1952. Default decree of condemnation and destruction.

**3832. Adulteration and misbranding of male hormone tablets. U. S. v. 76 Boxes, etc. (F. D. C. No. 33289. Sample Nos. 32442-L, 32445-L, 32449-L.)**

LIBEL FILED: June 12, 1952, Western District of Arkansas.

ALLEGED SHIPMENT: On or about March 28 and April 22, 1952, by Captivante Laboratories, from New York, N. Y.

PRODUCT: *Male hormone tablets*. 76 boxes, 31 boxes, and 161 boxes, each containing 60 tablets of the article at Hot Springs, Ark., in the possession of the Yale Pharmacal Co., together with a number of accompanying form letters commencing with "Confidentially this letter can change your whole life," "Personal private gland information for men only," "Dear Customer: We thank you for your recent order," and "Dear Customer: In checking our files," and a number of leaflets entitled "Request for progress report on your case" and "Discover new, safe, more effective combination of male sex hormones." Some of the form letters and leaflets were printed at New York, N. Y., and others were printed locally.

Analysis showed that each tablet of the article in the 76-box lot contained not more than 1.2 mg. of methyltestosterone and not more than a trace of ethinyl-estradiol.

LABEL, IN PART: (76-box lot) "Yale Testrex Male Sex Hormones 60 Tablets—Super-Strength (Double Potency) \* \* \* Ingredients per tablet 5 mg. Methyl Testosterone with Ethinyl Estradiol .002," (31-box lot) "Yale Testrex