

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

Male Sex Hormones 60 Tablets * * * Ingredients per tablet 2.5 mg. Methyl Testosterone with Ethinyl Estradiol .001," and (161-box lot) "Yale Testrex Male Sex Hormones 60 Tablets * * * Ingredients per tablet 2.5 mg. Methyl Testosterone with Ethinyl Estradiol .0025 mg." -

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article (all lots) differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), certain statements in the accompanying form letters and leaflets were false and misleading since the article (all lots) was not capable of fulfilling the promises of benefit stated and implied. The statements represented and suggested that the article would be effective to restore one's masculine drive, ambition, energy, and ability to do things one wants to do; that it would enable one to lead happier, more contented, and more forceful business and home lives; that it would be effective in rejuvenating men; that it would be effective to correct sex hormone deficiencies; that it would be effective in the treatment of the symptoms of the male change of life, such as aches and pains, tired out feeling, lack of desire to enjoy one's self, nervousness, fear, and frustration; that it would be effective to restore prematurely old men to useful, active lives; that use of the article would result in new vigor, new vitality, increased virility, added strength, and new energy; that the article would give one a new lease on life, enable weak effeminate men to become more masculine, restore waning physical and mental powers in men, and enable aging men to recapture the pleasures of their youth.

The article was adulterated and misbranded when introduced into and while in interstate commerce, and it also was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 23, 1952. Default decree of condemnation and destruction.

3833. Adulteration and misbranding of Livocomp capsules. U. S. v. 48 Bottles, etc. (F. D. C. No. 33346. Sample No. 4273-L.)

LABEL FILED: July 11, 1952, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about May 9, 1952, by Nysco Laboratories, Inc., from Long Island City, N. Y.

PRODUCT: *Livocomp capsules.* 48 bottles, each containing 100 capsules, of the product at Richmond, Va. Examination showed that it contained 74 percent of the declared amount of vitamin B₁.

LABEL, IN PART: (Bottle) "100 Capsules No. 1001 Livocomp For secondary anemia due to iron deficiency * * * Each Capsule Contains: * * * Vitamin B-1 333 USP Units-1 MDR."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, "Each Capsule Contains: * * * Vitamin B-1 333 USP Units 1 MDR."

Misbranding, Section 502 (a), the label statement "Each Capsule Contains: * * * Vitamin B-1 333 USP Units 1 MDR" was false and misleading as applied to the article, which contained less than the declared amount of vitamin B₁.

The libel alleged also that a quantity of Improcal tablets was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.