

sented and suggested that the article would be efficacious to relieve pain and aches in the ear and buzzing and water in the ear and to soften wax in the ear, whereas the article would not be efficacious for such purposes.

DISPOSITION: November 7, 1952. The defendant having entered a plea of nolo contendere to counts 1, 2, and 3, which related to the *Beatsol Rectifiers*, and a plea of guilty to counts 4, 5, and 6, which related to the *Beatsol Drawing Salve* and the *Beatsol Earache Liquid*, the court imposed a fine of \$100 on each of the first three counts of the indictment and a fine of \$200 on each of the remaining three counts, a total fine of \$900.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3830. Adulteration and misbranding of imitation Premarin tablets. U. S. v. Max Lippmann. Plea of nolo contendere. Fine, \$500. (F. D. C. No. 32695. Sample No. 23101-L.)

INFORMATION FILED: March 13, 1952, District of New Jersey, against Max Lippmann, Paterson, N. J.

INTERSTATE SHIPMENT: On or about April 4, 1950, from the State of New York into the State of New Jersey.

ALLEGED VIOLATION: Between the approximate dates of April 4 and August 31, 1950, while a number of tablets of the drug were being held for sale after shipment in interstate commerce, the defendant caused a number of tablets to be repackaged into envelopes and labeled and marked, in part, as "Premarin Tablets 1.25 mg.," and to be sold and delivered to various retail druggists, which acts resulted in the repackaged tablets being adulterated and misbranded.

NATURE OF CHARGE: Adulteration Section 501 (c), the strength of the repackaged tablets differed from, and their quality fell below, that which they purported and were represented to possess. The repackaged tablets purported to be and were represented as 1.25 mg. Premarin tablets, manufactured by Ayerst, McKenna & Harrison, Ltd., New York, N. Y., which tablets contain conjugated water-soluble estrogens equivalent to 1.25 mg. of sodium estrone sulfate, whereas the repackaged tablets were not 1.25 mg. Premarin tablets and did not contain conjugated water-soluble estrogens; and Section 501 (d) (2), a drug containing no conjugated water-soluble estrogens had been substituted for 1.25 mg. Premarin tablets, a drug which contains conjugated water-soluble estrogens.

Misbranding, Section 502 (a), the statement "Premarin Tablets 1.25 mg." on the label of the repackaged tablets was false and misleading. The statement represented and suggested that the repackaged tablets were 1.25 mg. Premarin tablets, manufactured by Ayerst, McKenna & Harrison, Ltd., New York, N. Y., which tablets contain conjugated water-soluble estrogens equivalent to 1.25 mg. of sodium estrone sulfate, whereas the repackaged tablets were not 1.25 mg. Premarin tablets and did not contain conjugated water-soluble estrogens; and, Section 502 (i) (2), the repackaged tablets were an imitation of another drug in that such tablets resembled in outward appearance genuine 1.25 mg. Premarin tablets, and were labeled, sold, and distributed as genuine 1.25 mg. Premarin tablets containing conjugated water-soluble estrogens equivalent to 1.25 mg. of sodium estrone sulfate, which are manufactured by Ayerst, McKenna & Harrison, Ltd., New York, N. Y., but the re-

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