

DISPOSITION: September 30, 1953. Default decree of condemnation. The court ordered that the devices and testimonial letters be delivered to the Food and Drug Administration.

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

4191. Adulteration of posterior pituitary injection. U. S. v. Cleo O. Bedwell.
Plea of nolo contendere. Fine, \$50. (F. D. C. No. 33778. Sample Nos. 17304-L, 17329-L.)

INFORMATION FILED: June 2, 1953, Southern District of California, against Cleo O. Bedwell, president of the Coast Chemical Co., a corporation, Los Angeles, Calif.

ALLEGED VIOLATION: On or about January 18 and May 1, 1952, the defendant caused to be given to firms engaged in the business of shipping drugs in interstate commerce, invoices containing guaranties to the effect that the *posterior pituitary injection* listed in the invoices and delivered by the defendant under the guaranties would not be adulterated. On or about January 18 and May 1, 1952, the defendant caused to be delivered to the holders of the guaranties, at Los Angeles, Calif., quantities of *posterior pituitary injections* which were adulterated.

LABEL, IN PART: (Vials) "Post Pituitary Solution U. S. P. * * * Towne, Paulsen & Co., Inc. Distributors Pasadena, Cal." and "Obstétrical Pituitary U. S. P. * * * Medical Specialties Co. Los Angeles, Calif."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Posterior Pituitary Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since each cubic centimeter of the article possessed an activity equivalent to less than 8.5 U. S. P. posterior pituitary units, whereas the standard provides that each cubic centimeter of posterior pituitary injection possesses an activity equivalent to not less than 8.5 U. S. P. posterior pituitary units; and the difference in strength of the article from the standard was not plainly stated, or stated at all, on its label.

DISPOSITION: August 17, 1953. The defendant having entered a plea of nolo contendere, the court fined him \$50.

4192. Adulteration and misbranding of Yale Testrex tablets. U. S. v. Captivante Laboratories, Inc., and Paul Thomas. Pleas of guilty. Fine of \$150 against corporation and \$300 against individual. (F. D. C. No. 34860. Sample Nos. 32442-L, 32449-L, 34692-L.)

INFORMATION FILED: May 6, 1953, Southern District of New York, against Captivante Laboratories, Inc., New York, N. Y., and Paul Thomas, president of the corporation.

ALLEGED SHIPMENT: On or about March 28, April 22, and May 29, 1952, from the State of New York into the State of Arkansas.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess. Some of the tablets were represented to contain 2.5 milligrams of methyltestosterone and other tablets were represented to contain 5 milligrams of methyltestosterone, whereas the tablets contained less methyltestosterone than represented.

Misbranding, Section 502 (a), the label statements "Ingredients per tablet 2.5 mg. [or "5 mg."] Methyl-Testosterone" were false and misleading.

DISPOSITION: September 14, 1953. The defendants having entered pleas of guilty, the court fined the corporation \$150 and the individual \$300.

4193. Adulteration and misbranding of Merestrin tablets. U. S. v. 166 Bottles
* * * (F. D. C. No. 35329. Sample No. 72255-L.)

LABEL FILED: June 22, 1953, District of Columbia.

ALLEGED SHIPMENT: On or about December 30, 1952, by Hance Bros. & White Co., from Philadelphia, Pa.

PRODUCT: 166 bottles of *Merestrin tablets* at Washington, D. C. Analysis showed that the product contained 74 percent of the declared amount of the estrogenic ingredient.

LABEL, IN PART: (Bottle) "100 S. C. Yellow Tablets Merestrin Tablets Each Yellow Tablet Contains: 1.25 mgs. of Estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess since the article contained but 74 percent of the declared amount of the estrogenic ingredient.

Misbranding, Section 502 (a), the label statement "Each Yellow Tablet Contains: 1.25 mgs. of Estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate" was false and misleading as applied to the article, which contained but 74 percent of the declared amount of conjugated estrogens calculated as sodium estrone sulfate.

DISPOSITION: July 22, 1953. Irwin T. Sealfon, trading as the Meredyth Co., Washington, D. C., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for reprocessing under the supervision of the Department of Health, Education, and Welfare. The tablets were reprocessed by washing for the removal of their coating and by regrinding for the adding of estrogens.

4194. Adulteration and misbranding of vitamin B complex. U. S. v. 225 Vials
* * * (F. D. C. No. 35447. Sample No. 62726-L.)

LABEL FILED: August 4, 1953, Western District of Tennessee.

ALLEGED SHIPMENT: On or about May 1, 1953, by the Medical Chemicals Corp., from Chicago, Ill.

PRODUCT: 225 vials of *vitamin B complex* at Memphis, Tenn. Analysis showed that the product contained 73 percent of the declared amount of vitamin B₁ (thiamine hydrochloride).

LABEL, IN PART: "10 cc multiple dose sterile vial vitamin B complex Each cc contains: thiamine HCL. 100 mgs."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 100 milligrams of thiamine hydrochloride per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc contains: thiamine HCL. 100 mgs." was false and misleading as applied to the article, which contained less than 100 milligrams of thiamine hydrochloride per cubic centimeter.