

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

3221. Misbranding of Metandren Linguets and Neo-Hombreol tablets. U. S. v. United Research Laboratories, Inc., and Robert Roberts. Pleas of nolo contendere. Corporation fined \$75; individual, \$3. (F. D. C. No. 28119. Sample Nos. 12371-K, 12376-K, 47160-K.)

INFORMATION FILED: January 20, 1950, Eastern District of Pennsylvania, against United Research Laboratories, Inc., Philadelphia, Pa., and Robert Roberts, vice president of the corporation.

ALLEGED SHIPMENT: On or about April 22, June 17, and July 6, 1949, from the State of Pennsylvania into the States of New Jersey and West Virginia.

PRODUCT: Examination disclosed that the products consisted of methyl testosterone.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "Hormones and the Male Climacteric" were false and misleading. The statements represented and suggested that the articles would be adequate treatments for headache, excessive fatigue, nervousness irritability, insomnia, decreased memory and power of concentration, a feeling of uncertainty and tremulousness, vasomotor disturbances, such as flashes, sweats, chills, and parasthesias, vague pains, particularly in the region of the bladder, a loss of force in the urinary stream, clinical signs of prostatic hyperplasia or nonspecific prostatitis, decrease in libido and potency, symptoms of climacteric syndrome, and involuntional melancholia; that the articles would prevent the "clock of life from running down"; and that they would permit the user to resume with confidence normal business and social activities. The articles would not be adequate treatments for the conditions represented; they would not prevent the "clock of life from running down"; and they would not permit the user to resume with confidence normal business and social activities.

Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration since each *Metandren Linguet* and *Neo-Hombreol tablet* contained 5 milligrams of methyl testosterone; and the labeling of the articles failed to warn that their use may result in sterility, and that their use by individuals with carcinoma of the prostate may result in acceleration of the malignant growth.

Further misbranding, Section 502 (j), the articles were dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in their labeling. Each *Metandren Linguet* and *Neo-Hombreol tablet* contained 5 milligrams of methyl testosterone, and the use of articles containing 5 milligrams of methyl testosterone, i. e., in each *Metandren Linguet* and *Neo-Hombreol tablet*, with the frequency prescribed, recommended, and suggested in the labeling, namely, 3 to 4 Linguets (tablets) per day, would be dangerous to health since such use may result in sterility, and since their use by individuals with carcinoma of the prostate may result in acceleration of the malignant growth.

DISPOSITION: May 3, 1950. Pleas of nolo contendere having been entered, the court fined the corporation \$75 and the individual \$3.