

potency and libido. The article was not the true male sex hormone, and it would not fulfill the promises of benefit stated and implied. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the following directions on the labeling of different portions of the article were not adequate directions for use: "Dosage: 1 tablet daily Important: In case of pronounced male sex hormone deficiency take 3 tablets daily for ten days. After 10 day period take 1 tablet daily" and "Dosage: 1 tablet daily Important: In case of pronounced male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10 day period take 1 tablet daily before meals or as directed by your physician."

Female sex hormone tablets. Misbranding, Section 502 (a), certain statements in accompanying leaflets of the same titles as those referred to above were false and misleading. These statements represented and suggested that the article would relieve and postpone the conditions associated with middle age; that the article would bring prompt relief from hot flashes, emotional disturbances, and other manifestations associated with the menopause; and that it would be efficacious to bring about a steady readjustment and to help overcome most menopausal conditions in women approaching or passing through the menopause. The article would not be efficacious for the purposes represented. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions for use "Just One Tablet A Day" and "In case of pronounced female sex hormone deficiency take 3 tablets daily before meals for 10 days. After the 10 day period take 1 tablet daily or as directed by your physician," borne on the labeling of the article, were not adequate directions for use. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and duration of administration, in such manner and form as are necessary for the protection of users, since each tablet of the article contained .1 milligram of crystalline alpha estradiol; and the labeling of the article failed to warn that use of the article in the dosage and with the duration of administration recommended on its labeling may result in uterine bleeding and damage to the ovaries. Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling since each tablet contained .1 milligram of crystalline alpha estradiol, and the use of a drug containing .1 milligram of crystalline alpha estradiol with the frequency prescribed, recommended, and suggested in its labeling, namely, "3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily," would be dangerous to health since use of the article may result in uterine bleeding and damage to the ovaries.

DISPOSITION: July 13, 1949. A plea of not guilty having been entered, the case came on for trial before the court without a jury. At the conclusion of the trial, the court returned a verdict of guilty and fined the defendant \$400.

2932. Misbranding of Male Hormone tablets, Menformon Dosules, Female tablets, and Metandren Linguets. U. S. v. El-O-Pathic Pharmacy, Inc., and Martin A. Clemens (as manager and director of the corporation and as an individual trading as M. A. Clemens Pharmacy). Pleas of not guilty. Tried to the court; verdict of guilty. Fine of \$700 against corporation and \$700 against Martin A. Clemens. (F. D. C. No. 25607. Sample Nos. 30046-K, 30047-K, 30068-K, 30919-K, 31204-K, 31208-K, 31217-K to 31220-K, incl., 31610-K.)

INFORMATION FILED: March 22, 1949, Southern District of California, against the El-O-Pathic Pharmacy, Inc., Los Angeles, Calif., and Martin A. Clemens, manager and director of the corporation and trading individually as the M. A. Clemens Pharmacy, Los Angeles, Calif.

ALLEGED VIOLATION: The El-O-Pathic Pharmacy, Inc., Los Angeles, Calif., and Martin A. Clemens, acting as manager and director of the El-O-Pathic Pharmacy, Inc., and trading individually as the M. A. Clemens Pharmacy, on or about October 26 and 30, November 1 and 6, and December 8 and 28, 1947, and January 9 and 19, 1948, caused the introduction into interstate commerce, at Los Angeles, Calif., for delivery to Tucson and Phoenix, Ariz., and Seattle, Wash., of quantities of products labeled *Male Hormone tablets*, *Female tablets*, *Menformon Dosules* and *Metandren Linguets*. When introduced into interstate commerce, the drugs were accompanied by circulars entitled "Male and Female Sex Hormones."

The defendants also made over-the-counter sales of three lots of the drug labeled *Male Hormone*. The drug had been shipped in interstate commerce from Nutley, Bloomfield, and Summit, N. J., to Los Angeles, Calif., and while held for sale after such shipment, it was repacked by the defendants into envelopes and sold to various persons without a physician's prescription, accompanied by circulars entitled "Male and Female Sex Hormones," which acts of the defendants resulted in the drug being misbranded.

LABEL, IN PART: (Male Hormone) "Each tablet contains 25 mg. [or "5 mg."] testosterone the form of the true male [all labels with one exception contained the word "sex"] hormone which is most highly effective for administration by mouth"; (Metandren Linguets) "Each linguet contains 5 mg. of Metandren (methyltestosterone), orally active androgen"; (Menformon Dosules) "(Female Sex Hormone Ointment in individual dose containers for accuracy of dosage). Each Dosule contains 1 gram of ointment. The active ingredient of Menformon Dosules is Non-Crystalline Estrone in natural combination with insignificant quantities of other naturally occurring female sex hormones (equilin and equilenin) derived from pregnant mare's urine. The content of estrogenic substance present in each dosule represents the estrus producing activity of 2000 International units of 0.2 mg. of standard crystalline keto-hydroxyestratriene (estrone)." The *Female tablets* bore no labeling on the box but the word "Female."

NATURE OF CHARGE: *Male Hormone tablets*. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. The statements represented and suggested that the article would stimulate growth and development of the sex organs, and the male sex characteristics such as distribution of hair, muscular development, and depth of voice; that it would correct lack of sexual power and impotence; that it would relieve and postpone the many conditions associated with middle age and would improve the sense of well-being; that it constituted an adequate treatment for flushes, sweats, chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness, and lack of physical strength; that use of the article would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that the article would impart a better attitude toward social life and would cause nervousness, exhaustion, and melancholy to disappear in the average man in his late forties. The article would not constitute an adequate treatment for the conditions represented and would not fulfill the promises of

benefit stated and implied. Further misbranding, Section 502 (f) (2), the labeling of the four shipments of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since each tablet contained 25 milligrams (or 5 milligrams) of male hormone (methyl testosterone); and the labeling of the four shipments failed to warn that use of the product may result in sterility and that its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. Further misbranding, Section 502 (j), the article in all shipments and sales was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling since each tablet contained 25 milligrams (or 5 milligrams) of male hormone (methyl testosterone), and the use of an article containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended, and suggested in the labeling, namely, as directed on some of the box labels, "1-2 tablets daily" or "2 tablets 3 times daily," and as directed in the circular "One tablet a day," would be dangerous to health in that such use of the article may result in sterility; and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

Menformon Dosules. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. The statements represented and suggested that the article would be efficacious to develop the female breasts, and to stimulate mammary growth and result in definite breast growth of considerable degree, and that it would be efficacious in the treatment of underdeveloped breasts. The article would not be efficacious for such purposes.

Female tablets. Misbranding, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article; and, Section 502 (f) (1), the labeling of the article bore no directions for use. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since each tablet of the article contained 0.5 milligrams of alpha-estradiol; and the labeling of the article failed to warn that its unrestricted use may result in injury to the female generative system and that its use by females with early and incipient carcinoma of the breast, cervix, and uterus may result in acceleration of the malignant growth.

Metandren Linguets. Misbranding, Section 502 (a), the labeling of the article contained false and misleading statements of the same nature as the false and misleading statements described above, with respect to the *Male Hormone tablets*; Section 502 (f) (1), the labeling of the article bore no directions for use. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form as are necessary for the protection of users, since each linguet of the article contained 5 milligrams of male hormone (methyl testosterone); and the labeling of the article failed to warn that its unrestricted use may result in sterility and that unrestricted use of the

article by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

DISPOSITION: Pleas of not guilty having been entered, the case came on for trial before the court without a jury on June 22, 1949. On July 13, 1949, the court returned a verdict of guilty on all counts as to both defendants and imposed a fine of \$700 against the corporation and \$700 against the individual.

✓ **2933. Misbranding of Metandren Linguets. U. S. v. George H. McKinlay (Health Chemicals). Plea of not guilty. Tried to the court. Verdict of guilty. Fine, \$300. (F. D. C. No. 25603. Sample Nos. 24585-K, 28038-K, 30045-K.)**

INFORMATION FILED: March 28, 1949, Southern District of California, against George H. McKinlay, trading as Health Chemicals, Los Angeles, Calif.

ALLEGED SHIPMENT: On or about October 30, 1947, and April 1 and 26, 1948, from the State of California into the States of North Dakota, Colorado, and Arizona.

LABEL, IN PART: "Metandren Linguets * * * Compressed water especially designed for absorption from under the tongue or inside the cheek. Each linguet contains 5 mg. of Metandren (methyltestosterone), orally active androgen."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements relating to the article in an accompanying circular entitled "Hormones and the Male Climacteric" were false and misleading. The statements represented and suggested that the article would be an adequate treatment 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 paresthesias, vague pain, 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; and that the article would prevent the "clock of life" from running down and would permit the user to resume with confidence normal business and social activities. The article would not be an adequate treatment for the conditions represented; it would not prevent the "clock of life" from running down; and it would not permit the user to resume with confidence normal business and social activities.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warning against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, since each linguet of the article contained 5 milligrams of male hormone (methyl testosterone); and the labeling failed to warn that the use of the article may result in sterility and that its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. Further misbranding, Section 502 (j), the article was dangerous to health, when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, since each linguet of the article contained 5 milligrams of male hormone (methyl testosterone), and the use of a drug containing 5 milligrams of male hormone in each linguet with the frequency prescribed, recommended, and suggested in the labeling, namely, "3 to 4 Linguets per day," would be dangerous to health since use of the article may