

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**- DRUGS FOR HUMAN USE**

3421. Misbranding of Estinyl tablets, Hormotone "T" tablets, Oreton-M tablets, Neo-Hombreol tablets, and Metandren Linguets. U. S. v. Ace Mail Order Co. and Mendel Bernstein. Pleas of nolo contendere. Each defendant fined \$750. (F. D. C. No. 29421. Sample Nos. 4737-K, 19885-K, 19888-K, 19893-K to 19895-K, incl.)

INFORMATION FILED: June 27, 1950, District of New Jersey, against the Ace Mail Order Co., a partnership, East Orange, N. J., and Mendel Bernstein, a partner in the firm.

ALLEGED SHIPMENT: On or about June 2 and 24 and July 11, 1949, from the State of New Jersey into the States of Massachusetts and Tennessee.

LABEL, IN PART: "Schering Tablets Estinyl * * * Brand of Ethinyl Estradiol * * * Each tablet contains 0.05 mg. Crystalline Pure Ethinyl Estradiol Schering Corporation Bloomfield, New Jersey," "Schering Estinyl tablets .05 m. g.," "Hormotone 'T' Estrogenic Hormones * * * Each tablet contains estrogens (estradiol, estrone) equivalent to 1,000 International Units and 1/20 gr. thyroid * * * G. W. Carnrick Co. Newark, N. J.," "Schering Oreton-M * * * Brand of Methyl Testosterone Crystalline pure testicular hormone preparation * * * Schering Corporation Bloomfield, New Jersey * * * Each tablet contains 10 mg. Methyl Testosterone," "Tablets 10 mg. each Neo-Hombreol (M) 'Roche-Organon' * * * (Androgenic Preparation—Brand of Methyl Testosterone) * * * Roche-Organon, Inc. Nutley, New Jersey Organon, Inc. Formerly known as Roche-Organon, Inc. Orange, New Jersey," and "Metandren Linguets Brand of Methyltestosterone U. S. P. * * * 10 mg. * * * Ciba Pharmaceutical Products, Inc. Summit, New Jersey."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use since the labeling bore no directions for use.

Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear such adequate warnings against use in those pathological conditions where their 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. The labeling of the *Estinyl tablets* failed to warn that their use by the male may result in sterility and loss of sexual power and may have a feminizing effect upon the male; that their use by the female may result in sterility, injury to the female generative system, and bleeding from the uterus; and that their use by females with carcinoma of the breast, cervix, and uterus may result in acceleration of malignant growth. The labeling of the *Hormotone "T" tablets* bore no warnings against unsafe dosage and duration of administration. The labeling of the *Oreton-M tablets*, *Neo-Hombreol tablets*, and *Metandren Linguets* failed to warn that the use of such tablets and linguets may result in sterility and that their use by individuals with carcinoma of the prostate may result in acceleration of the malignant growth.

DISPOSITION: March 30, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$750 against each defendant.