

LABEL, IN PART: (Package) "Male Hormone (methyl testosterone) combined with Vitamin B₁ * * * Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B₁ (Thiamin Hydrochloride)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label on the packages of the article contained statements which represented and suggested that when taken as directed, the article would be efficacious in the treatment of male hormone deficiency, which statements were false and misleading since the article when taken as directed, was not efficacious for such purpose; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to state all of the diseases or conditions of the body for which the article was intended; and, Section 502 (f) (2), the labeling of the article failed to bear such 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 the technical medical terminology in which the cautionary statement on the labeling was couched, namely,

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardio-vascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician.

was inadequate to warn the ordinary lay user that use of the product may accelerate the malignant growth of the prostate gland or may cause sterility.

DISPOSITION: August 27, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3586. Adulteration of extract of Glycyrrhiza. U. S. v. MacAndrews & Forbes Co. Plea of guilty. Defendant placed on probation for 2 years. (F. D. C. No. 30119. Sample No. 81757-K.)

INFORMATION FILED: April 26, 1951, District of New Jersey, against MacAndrews & Forbes Co., a corporation, Camden, N. J.

ALLEGED SHIPMENT: On or about October 13, 1950, from the State of New Jersey into the State of Tennessee.

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), the article had been prepared under insanitary conditions whereby it may have become contaminated with filth.

The information alleged also that the defendant had shipped in interstate commerce a quantity of licorice paste which was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 17552.

DISPOSITION: July 11, 1951. A plea of guilty having been entered, the court placed the defendant on probation for 2 years on the count charging adulteration of the *Glycyrrhiza*. (The defendant was fined \$250 on the count charging adulteration of licorice paste.)