

the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling was couched was inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of cancer of the prostate gland or may cause sterility; 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling since each tablet of the article contained 10 mg. of methyltestosterone (a male hormone), and the use of a drug containing 10 mg. of methyltestosterone in each tablet with the frequency and duration prescribed, recommended, and suggested, to wit, as directed on the box label, "One tablet upon arising before breakfast or one tablet shortly before retiring . . . The maintenance dosage can be extended from three to six months, under supervision of a physician," would be dangerous to health since such use of the drug may result in sterility and such use by individuals with carcinoma of the prostate may result in acceleration of the malignant growth; and 503 (b) (4)—the article was a drug subject to 503 (b) (1) (B), and its label, prior to dispensing, failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Vita-40 tablets. 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for providing pep, vitality, new vigor, new life, new hope, and renewed vitality in men over 40 years of age, and for overcoming male sexual weakness, especially in men over 40 years of age; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

PLEA: Guilty.

DISPOSITION: 10-8-56. Corporation—\$1,000 fine; individual—\$1,000 fine and placed on probation for 5 years.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5222. Pega Palo. (F. D. C. No. 39892. S. No. 60-028 M.)

QUANTITY: 600 labeled pkgs. and an unknown quantity of bulk vine at Chicago, Ill., in possession of A-1 Import Co.

SHIPPED: During December 1956 and January 1957, from the Dominican Republic.

LABEL IN PART: (Pkg.) "Pega Palo Vine, Chicago, Illinois."

ACCOMPANYING LABELING: Sheets reading, in part, "Gentlemen * * * Description: Product is an aphrodisiac * * * Sincerely Yours: Harold Baum: A-1 Import Co." and "Detailed Information as to the use & Cost of Pega Palo Vines: * * * Very Truly Yours Harold Baum: A-1 Import Co."

LIBELED: 3-8-57, N. Dist. Ill.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use of the article as an aphrodisiac; and 505 (a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 3-29-57. Default—delivered to the Food and Drug Administration.

5223. Pega Palo. (F. D. C. No. 39891. S. No. 57-606 M.)

QUANTITY: 25 lbs. at Miami, Fla.