SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5221–5240

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 502 (l), the article purported to be and was represented as a drug composed wholly or partly of chlortetracycline or a derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5221. Methyltestosterone tablets and Vita–40 tablets. (F. D. C. No. 38514. S. Nos. 39–578 L, 40–262 L, 74–711 L, 11–082 M.)

INDICTMENT RETURNED: 4–4–56, S. Dist. Calif., against Vita Pharmacals, Inc., Los Angeles, Calif., and Floyd L. Clemens, president.

ALLEGED VIOLATION: The indictment alleged that a quantity of methyltestosterone had been shipped on or about 8–19–54 from New York to California, where it was fabricated into tablets and delivered to the defendants; that following such delivery and while such methyltestosterone in tablet form was being held for sale after shipment in interstate commerce, the defendants caused a quantity of the article in tablet form to be dispensed on 9–18–54 in a box without a prescription and an additional quantity of the article in tablet form to be repacked into boxes and accompanied by certain labeling in the period of 9–15–54 to 9–22–54; that the defendants' act of causing the dispensing of a quantity of the article in tablet form was an act done contrary to the provisions of 503 (b) (1), which resulted in the article being misbranded while

held for sale; and that the defendants' act of causing a quantity of the article in tablet form to be accompanied by certain labeling resulted in such quantity of the article being misbranded as described below.

The indictment alleged also that the defendants, on 7–24–54 and 8–4–54, caused the introduction into interstate commerce, for delivery to Phoenix, Ariz., and Houston, Tex., of *Vita–40 tablets*, misbranded as described below.

LABEL IN PART: (BOX) "VITA HORMONES 50 Tablets Each Tablet Contains 10 Mg. Methyltestosterone SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are presribed or recommended by a physician for palliative relief of such symptoms. Distributed by VITA PHARMACALS, INC. * * * It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician. 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 cardiovascular 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" and "VITA–40 TABLETS * * * Distributed by VITA PHARMACAL COMPANY."

ACCOMPANYING LABELING: Leaflets entitled "Price List of New Male Hormone Tablets" and "The Evidence"; placard entitled "Doctor Says Hormones Key to Rejuvenation"; leaflets containing a reproduction of an article entitled "Hormone Dosages Safe, Doctors Told" from the Los Angeles Times; folders containing a reproduction of an article entitled "Hormones For Men" from the American Weekly.

CHARGE: *Methyltestosterone tablets* with the aforesaid accompanying labeling. 502 (a)—this labeling contained false and misleading representations that the article was an adequate and effective treatment for providing renewed vigor, endurance, strength, and vitality in men over 40, replenishing male vigor in men over 40, replenishing power vitiated by age and the stress and strain of modern living, relieving varied symptoms of mental and bodily stress in persons of later years, overcoming imbalance in the glandular system resulting in insomnia and other nervous symptoms, overcoming the signs of the "male climacteric," overcoming fatigue, nervousness, and irritability in old men, overcoming excessive perspiration and progressive numbness of the body, making old persons younger and healthier, and making old persons more active physically and mentally; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; 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 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.