

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 5281-5300**

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy or decomposed substance; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its strength differed from 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 purity or 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 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (l), the article purported to be and was represented as a drug composed partly of a kind of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

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.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5281. Pyradex. (F. D. C. No. 40108. S. No. 60-314 M.)

QUANTITY: 65 vials at Detroit, Mich.

SHIPPED: 1-24-57, from Philadelphia, Pa., by Vitamix Corp.

LABEL IN PART: (Vial) "10 cc Multiple Dose Vial * * * Pyradex with Dextro Amphetamine Hcl * * * Intramuscular only * * * Each cc contains a sterile aqueous solution of Pyranisamine Maleate . . . 25 mgm. * * * Indications: Hay fever, Nonseasonal allergic and Vasomotor Rhinitis, Asthma, Urticaria, Eczema and Dermatitis. Dosage: 1cc intramuscularly daily."

LIBELED: 3-26-57, E. Dist. Mich.

CHARGE: 505 (a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 5-13-57. Default—destruction.

5282. Pega Palo vine. (F. D. C. No. 40122. S. No. 70-971 M.)

QUANTITY: 470 cellophane pkgs. at Kimball, S. Dak.

SHIPPED: 2-18-57, from A-1 Import Co., Chicago, Ill., by Oliver Olson.

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

ACCOMPANYING LABELING: Reprints of an article entitled "Pega Palo The Vine That Makes You Virile," from the January 1957 issue of Confidential magazine.

RESULTS OF INVESTIGATION: Examination showed that each package of the article contained a piece of dried, woody, vine-like material.

LIBELED: 4-5-57, Dist. S. Dak.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use as an aphrodisiac, which was the purpose for which the drug was intended; 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: 5-9-57. Consent—portion of article delivered to Food and Drug Administration and remainder destroyed.

5283. Pega Palo vine. (F. D. C. No. 40092. S. No. 72-887 M.)

QUANTITY: 33 cellophane pkgs. at Salt Lake City, Utah.

SHIPPED: On 1-31-57, D. H. Farrell and Al Cavey purchased the article from A-1 Import Co., Chicago, Ill., and personally transported it from Chicago to Salt Lake City.

ACCOMPANYING LABELING: Reprints of an article entitled "Pega Palo The Vine That Makes You Virile."

LIBELED: 3-20-57, Dist. Utah.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for its use as an aphrodisiac and as a sex rejuvenator, which were the purposes for which the article was intended; 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: 8-8-57. Default—the article and some of the reprints were delivered to the Food and Drug Administration, and the remainder of the reprints were destroyed.

5284. Pago (Pega) Palo vine. (F. D. C. No. 40096. S. No. 57-605 M.)

QUANTITY: 104 9-gram pkgs. at Miami Beach, Fla., in possession of Alfred J. Hardwick, d/b/a/ Bud Brownell.

SHIPPED: 12-21-56, from Dominican Republic, by Alfred J. Hardwick.

LABEL: (Pkg.) "Pago Palo Health Fountain of Youth Not For Sale To Persons Under 21 Years Of Age! For Steeping in Whiskey, Rum, Gin, Wine, Cognac, etc. Directions: Insert contents of pack into fifth of liquor. Allow to steep 3 days. For best results, wait one week. If more sweetness is desired, add raisins or caramel. Recommended Dosage: 3 ounces daily for three days. Thereafter 2 to 3 ounces weekly or at user's discretion. Note: Pago Palo in its vine form may be re-steeped repeatedly before its potency diminishes. This pack should constitute a one year's supply. Pago Palo Distributors * * * Hialeah, Fla."

RESULTS OF INVESTIGATION: The above packages were repacked from a 20-pound bulk shipment. Examination of the article showed it to consist of pieces of plant material resembling stem tissue. The pieces were 3 to 5 inches long and ¼- to ½-inch wide and appeared to be mostly flattened or longitudinally split stems. The surfaces of the whole stems appeared to be a thin brown bark, the interiors being hard and mildly woody with some pith areas. Splinters had no taste but a faintly musty odor.

LIBELED: 3-22-57, S. Dist. Fla.

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