

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 5301-5320**

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 (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 (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 partly of a kind of penicillin, chlortetracycline, or Chloromycetin, 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.

Publicity, Section 705 (a), the Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof; Section 705 (b), the Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

5301. Various drugs. (F. D. C. No. 39209. S. Nos. 23-845/6 M, 30-305 M, 31-774 M.)

INFORMATION FILED: 12-26-56, N. Dist. Ill., against Medical Chemical Corp., Chicago, Ill., and Bernard B. Speiser, president.

SHIPPED: Between 7-2-55 and 9-17-55, from Illinois to Arizona, Indiana, and Tennessee.

LABEL IN PART: (Vial) "Intramuscular-10 cc-Shake Well Triple Hormone Suspension Each cc Contains—Esterone U. S. P. 6 mg.—Testosterone U. S. P. 25 mg.—Progesterone 5 mg.—Pectin 0.35%—Thimerosal 1:20,000—Sodium Acetate 0.8% Distributed by Myers-Carter Labs., Inc. * * * Phoenix, Arizona," "Sterile Multiple Dose 10 cc Progesterone U. S. P. 50 mg/cc In Buffered Aqueous Suspension Pectin 0.2%—Thimerosal 1:20,000 Intramuscular Myers-Carter Laboratories, Inc. Phoenix, Arizona," and "Sterile 10 cc Vial Testosterone U. S. P. 50 mg/cc In aqueous suspension Sod. Acetate 0.8%—Pectin 0.35% Thimerosal 1:20,000 Intramuscular Average Dose: 25 mg. Mfg'd for G and G Pharmacal Co. Inc. South Bend, Ind."; (ampul) "A-50 10 cc. Calcium Gluconate U. S. P. 10% Solution W/V in ampul water no

preservative Intramuscular and Intravenous Morton Pharmaceuticals Inc. Ethical Distributors Memphis, Tenn."

RESULTS OF INVESTIGATION: Examination of the *calcium gluconate* showed that it was pyrogenic and that the other drugs involved were not sterile as represented but were contaminated with viable micro-organisms.

CHARGE: 501 (c)—the purity and quality of the *triple hormone suspension* and the *testosterone*, when shipped, fell below that which they purported and were represented to possess; 502 (a)—the labels of the *progesterone* and *testosterone*, when shipped, contained false and misleading statements that the articles were sterile; and 502 (j)—when shipped, the *calcium gluconate* was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Usual Dose: Adults, intravenous or intramuscular 1 Gram daily or on alternate days; for children, intravenous 0.02 to 0.5 Gram."

PLEA: Nolo contendere.

DISPOSITION: 5-29-57. \$1,250 fine, plus costs.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5302. Pega Palo vine and root. (F. D. C. No. 40131. S. No. 70-865 M.)

QUANTITY: 7 bags, ½ oz. each, and 1 bag, containing ¼ oz., of *Pega Palo vine*, and 1 ctn., containing 11 lbs. 9 oz., of *Pega Palo root*, at Iowa Falls, Iowa, in possession of Richard H. Snook, d/b/a Competition Chemicals.

SHIPPED: During January 1957, from the Dominican Republic and Haiti, by Richard H. Snook.

ACCOMPANYING LABELING: Leaflets entitled "Pega Palo Vines and Roots (Fortidom)" and reprints entitled "Pega Palo The Vine That Makes You Virile."

LIBELED: 4-8-57, N. Dist. Iowa.

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 505 (b) was not effective with respect to such drug; and 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use for the purpose for which it was intended, namely, as an aphrodisiac.

DISPOSITION: 5-20-57. Default—destruction.

5303. Pega Palo vine. (F. D. C. No. 40123. S. No. 54-372 M.)

QUANTITY: 439 cellophane envelopes at Yakima, Wash.

SHIPPED: 2-14-57, from Chicago, Ill., by A-1 Import Co.

ACCOMPANYING LABELING: Reprints of an article from the January 1957 issue of "Confidential" magazine entitled "Pega Palo The Vine That Makes You Virile" and leaflets headed "Pega Palo Vine Directions For Use."

RESULTS OF INVESTIGATION: The reprints were shipped from Chicago, Ill., by A-1 Import Co., and the leaflets were printed locally.

Examination showed that the article was a dried, woody, vine-like material.

LIBELED: 4-10-57, E. Dist. Wash.

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